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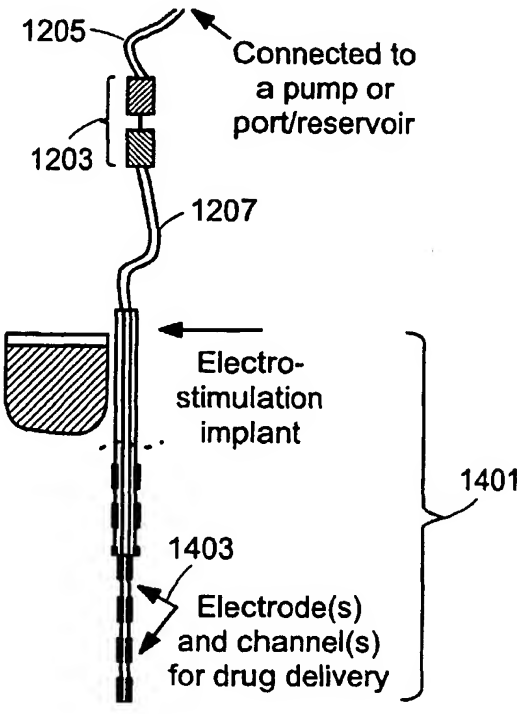

(57) Abstract: Implantable fluid delivery systems and implantable electrodes (203) are provided. The fluid delivery systems may include an implantable fluid source (113), a first catheter (109) in fluid communication with the implantable fluid source, and an implantable micro-valve (101) in fluid communication with the first catheter. The electrodes include a front end (2007) and back end (2005) for ease of implantation. One or more of the electrodes may be combined with a fluid delivery system to provide fluid to the body of a subject.

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Implantable Fluid Delivery Apparatuses and Implantable Electrode

Technical Field and Background Art

The present invention relates to implantable devices and, more particularly, to implantable fluid delivery apparatuses and an implantable electrodes.

Background Art

Fluid delivery systems and devices are often used to provide pharmaceuticals to the body of a human or animal subject. Such systems and devices may employ catheters for fluid delivery. It is also known in the art to implant electrodes and electrical prosthesis in the body to provide electrical stimulation to internal organs and tissue.

For example, intra cochlear electrodes are intended to restore some sense of hearing by direct electrical stimulation of the neural tissue in proximity of an electrode contact. As more and more patients with significant and usable residual hearing are implanted with cochlear implants, it becomes imperative to use a minimally traumatic electrode. In addition, devices may be implanted in a subject when the subject is at a very young age and it may be necessary to re-implant several times during a lifetime. Each consecutive insertion of a cochlear implant may cause trauma to spiral ganglion cells to a minimum. Trauma to spiral ganglion cell is cumulative and cannot be undone in the present state of technology.

To reduce trauma to the organ or tissue, electrodes and catheters should be soft, flexible, and insertion forces should be minimum. Unfortunately, most cochlear implant electrodes on the market today require significant force to be inserted, even for distances which are much less than the full length of the scala tympani.

The required force to insert the electrode or catheter is related to the size, geometry, and the material used in the fabrication of the particular device. Material used in such devices includes materials for wires, contacts, functional metallic or polymer segment, and bulk material. The size of the electrode or catheter, the rigidity of the material used in the electrode or catheter, the hydrophobicity of the outer shell of the electrode array, the energy stored in one way or another in the electrode and the insertion process of the device have an impact on the amount and location of damages that will be inflected to the tissue of the labyrinthe during electrode placement. With respect to fluid delivery systems in general,

removal and replacement of the system or of particular parts of the system may also cause trauma and damage to living tissue.

Damage and trauma cause bleeding, inflammation, perforation of soft tissue, tears and holes into membranes, and fracture of thin osseous structures. The resulting damage to the inner ear, for example, may cause loss of surviving hair cells, retrograde degeneration of the dendrite which inervates the organ of Corti, and in the worst case, spiral ganglion cell death in the Rosenthal's canal. Cell death means quantitatively less neural tissue is available for stimulation, and qualitatively, that less frequency-tuned fibers are available to represent frequency information. Loss of dendrites without loss of spiral ganglion means that acoustic stimulation is no longer possible, and that no synergetic effects between acoustic and electric stimulation is available. Electro-acoustic synergetic effects may be critical for good sound discrimination in noisy environments.

Summary of the Invention

In accordance with a first embodiment of the invention, a fluid delivery system includes an implantable fluid source and a first catheter in fluid communication with the implantable fluid source. An implantable micro-valve is in fluid communication with the first catheter. The implantable fluid source may include a fluid port, pump, osmotic pump or a fluid reservoir which may or may not be refillable. In accordance with related embodiments, the fluid delivery system includes a second catheter in fluid communication with the implantable micro-valve. The implantable micro-valve may include a magnet. Similarly, the implantable micro-valve may be self-closing. In accordance with other related embodiments the fluid delivery system may include a switch for stopping fluid flow through the system and/or an electrode in communication with the fluid source or with the first catheter. The electrode may be part of a cochlear implant or other implantable prosthesis.

In accordance with another embodiment of the invention, a fluid delivery system includes an implantable fluid source and an implantable micro-valve in fluid communication with the fluid source. In accordance with this embodiment, the fluid source may be a canister which may be removed from the system.

In accordance with a further embodiment of the invention, an electrode for an implantable prosthesis includes a flexible front end including one or more metal contacts and a back end including one or more metal contacts. The flexible front end is substantially thinner than the back end such that forces required to introduce the flexible

front end to soft tissue are minimal. In accordance with related embodiments, the flexible front end and the back end are comprised of a polymer matrix and each of the metal contacts may be connected to a wire that runs through the polymer matrix. The flexible front end may comprise about one half the mass of the back end. In accordance with another related embodiment, the electrode may include one or more fluid outlets, and each of the fluid outlets is in communication with at least two least two fluid channels.

In accordance with a further related embodiment, the back end of the electrode may include at least two segments, the two segments being fully connected to one another prior to implantation and at least partially disconnected from one another following implantation. In accordance with additional related embodiments, the electrode may include a stopper disposed upon an outer wall of the electrode for limiting the extent of implantation and/or a connector disposed between the flexible front end and the back end such that the flexible front end may be separated from the back end.

In accordance with another embodiment of the invention, a cochlear implant includes an implantable housing, the implantable housing including a current source, and an electric lead in communication with the current source. The electric lead includes a fluid delivery channel and an electrode array including one or more fluid outlets is in communication with the fluid delivery channel.

In accordance with another embodiment of the invention, an implantable catheter for fluid delivery includes a flexible polymer based housing having an internal channel in fluid communication with an implantable fluid source and one or more outlets disposed on the housing, each of the outlets including at least two outlet channels. In accordance with related embodiments, the catheter includes an adjustable blocker for closing an incision through which the catheter is inserted and/or a reinforcing filament for increasing ease of implantation. The reinforcing filament may include a wire reinforcing and/or a hardened polymer.

In accordance with yet another embodiment of the invention, a icro-septum connector includes n implantable port connector having a septum and an implantable spear connector having a needle for insertion into the septum. The implantable port connector may include a fluid source in fluid communication with the needle, a compression ring for compressing the septum and a mechanism for guiding the needle as it is inserted into the septum. In accordance with related embodiments the micro-septum connector may also include a stopping device for preventing direct contact between the implantable port connector and the implantable spear connector and/or a locking device for preventing

disengagement of the needle from the septum. The micro-septum connecter may further include a port catheter in fluid communication with the implantable port connector and/or a bacterial filter disposed between the fluid source and port catheter or between the implantable port connector and the port catheter. The micro-septum connector may also include a spear catheter in fluid communication with the needle.

In accordance with another embodiment of the invention, an apparatus for delivering fluid to the body of a subject includes an implantable fluid source, a first catheter in fluid communication with the fluid source, and a micro-septum connector. The micro-septum connector includes an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle, and an implantable port connector having a septum into which the needle is inserted. In accordance with related embodiments, a second catheter is in fluid communication with the implantable port connector.

In accordance with a further embodiment of the invention, an apparatus for delivering fluid to the body of a subject includes a first catheter in fluid communication with a fluid source and a micro-septum connector. The micro-septum connector includes an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle, and an implantable port connector having a septum into which the needle is inserted. A second catheter is in fluid communication with the implantable port connector, and an implantable electronic prosthesis having one or more fluid channels is in fluid communication with the second catheter.

In accordance with another embodiment of the invention, an apparatus for delivering fluid to the inner ear of a subject includes a first catheter in fluid communication with a fluid source and a micro-septum connector. The micro-septum connector includes an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle, and an implantable port connector having a septum into which the needle is inserted. The apparatus also includes fixation device for affixing the implantable port connector to the inner ear of a subject and the fixation device may be affixed to a promontory bone of the subject.

In accordance with another embodiment of the invention, an apparatus for delivering fluid to the body of a subject includes an implantable fluid reservoir, the implantable fluid reservoir including a first septum, a catheter in fluid communication with the implantable fluid reservoir, and a first needle in fluid communication with the catheter. In accordance with related embodiments, a bacterial filter and/or a flow restrictor may be

disposed between the implantable fluid reservoir and the catheter. An anchor for affixing the first needle to the catheter may also be included, and the anchor may include a silicone plug and/or one or more metal rings. In accordance with other related embodiments, the apparatus may also include an access port in fluid communication with the first needle. The access port includes a second septum, the second septum including a micro reservoir; and a second needle in fluid communication with the micro reservoir. An anchor for affixing the second needle to the second septum may also be included, and the anchor may include one or more metal rings. The metal rings may be embedded in silicone.

In accordance with a further embodiment of the invention, an implantable access port for delivering fluid to the body of a subject includes an implantable septum, the implantable septum including a micro reservoir, and a needle in fluid communication with the micro-reservoir. The access port may include an anchor for affixing the needle to the implantable septum, and the anchor may include one or more metal rings that may be embedded in silicone.

In accordance with another embodiment of the invention, an implantable fluid source for delivery of fluid to the body of a subject includes an implantable fluid reservoir, the implantable fluid reservoir having at least one fluid channel, and a septum in fluid communication with the at least one fluid channel.

Brief Description of the Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1 is a graphical illustration of a fluid delivery system in accordance with an embodiment of the present invention;

Fig. 2 is a graphical illustration of a fluid delivery system fused to a cochlear implant in accordance with another embodiment of the invention;

Fig. 3 is a graphical illustration of a fluid delivery system implanted parallel to a cochlear implant in accordance with an embodiment of the invention;

Fig. 4 is a graphical illustration of a fluid delivery system in accordance with a further embodiment of the invention;

Fig. 5 is a graphical illustration of a fluid delivery system in accordance with another embodiment of the invention;

Fig. 6 is a graphical illustration of a fluid delivery system having a fluid canister in accordance with an embodiment of the invention;

Fig. 7 is a graphical illustration of a switch that may be implanted under the skin in accordance with the embodiments of Figs. 1-5;

Fig. 8 is a graphical illustration of a switch that may be implanted in the middle ear of a subject in accordance with the embodiments of Fig. 5;

Fig. 9 is a graphical illustration of a refillable reservoir in accordance with another embodiment of the invention;

Fig. 10 is a graphical illustration of a self closing valve in accordance with a further embodiment of the invention;

Fig. 11 is a graphical illustration of a fluid delivery system for delivery of fluid to the inner ear of a subject in accordance with another embodiment of the invention;

Fig. 12 is a graphical illustration of an implantable micro-septum connector configuration for use with a pump and delivery catheter in accordance with another embodiment of the present invention;

Fig. 13 is a graphical illustration of an implantable micro-septum connector configuration for use with a port or reservoir and delivery catheter in accordance with a further embodiment of the invention;

Fig. 14 is a graphical illustration of an implantable micro-septum connector configuration for use with an electronic prosthesis in accordance with another embodiment of the invention;

Fig. 15 is a graphical illustration of a micro-septum connector before connection of an implantable port connector and an implantable spear connector in accordance with the embodiments of Figs. 12-14;

Fig. 16 is a graphical illustration of a micro-septum connector after connection of the implantable port connector and the implantable spear connector in accordance with the embodiment of Fig. 15;

Fig. 17 is a graphical illustration of an apparatus for delivering fluid to the inner ear of a subject in accordance with a further embodiment of the invention;

Fig. 18 is a graphical illustration of a catheter in accordance with another embodiment of the invention;

Fig. 19 is a pictorial illustration of the catheter of Fig. 18 implanted in the ear of a subject;

Fig. 20 is a graphical illustration of an implantable electrode in accordance with another embodiment of the invention;

Fig. 21 is a graphical illustration of the electrode of Fig. 20 implanted in the inner ear of a subject;

Fig. 22 is a pictorial illustration of wires associated with the electrode of Figs. 20 and 21;

Fig. 23 is a graphical illustration of an implantable electrode for delivering fluid to the body of a subject in accordance with another embodiment of the invention;

Fig. 24 is a graphical illustration of the electrode of Fig. 23 implanted in the inner ear of a subject in accordance with a further embodiment of the invention;

Fig. 25 is a graphical illustration of a cross sectional view of the electrode of Fig. 23;

Fig. 26 is a graphical illustration of an electrode used in connection with an implantable housing in accordance with a further embodiment of the invention;

Fig. 27 is a graphical illustration of an implantable electrode in accordance with another embodiment of the invention;

Fig. 28 is a graphical illustration of a cross sectional view of the electrode of Fig. 27;

Fig. 29 is a graphical illustration of the electrode of Fig. 27 implanted in the inner ear of a subject;

Fig. 30 is a graphical illustration of the electrode of Fig. 27 including a clip for joining the segments;

Fig. 31 is graphical illustration of an apparatus for delivering fluid to the body of a subject in accordance with a further embodiment of the invention;

Fig. 32 is a graphical illustration of a needle of the embodiment of Fig. 31;

Fig. 33 is a graphical illustration of an implantable access port in accordance with another embodiment of the invention; and

Fig. 34 is a graphical illustration of an apparatus for delivering fluid to the body of a subject in accordance with Figs. 31-33.

Detailed Description of Specific Embodiments

Fig. 1 is a graphical illustration of a fluid delivery system in accordance with an embodiment of the present invention. For purposes of this embodiment, the fluid delivery

system is employed to deliver pharmaceuticals to, for example, the inner ear of a subject. However, the fluid delivery systems and apparatuses described herein may be used to deliver many different types of fluids to one or more internal areas of a subject's body. The system shown in Fig. 1 includes a biocompatible and sealed micro-valve **101** with an inner ear side **103** and a middle ear side **105**. The micro-valve **101** provides a secure path between the middle ear and the inner ear through the promontory bone **107** of the cochlea or through the round window. The connection may, for example, be to the scala tympani, vestibuli or scala media. The micro-valve **101** provides permanent access to the inner ear for fluid delivery of various viscosity and healing functions. The micro-valve **101** may be made of, for example, polymer, titanium (precision cut by laser micro-machining as can be produced by Kurtz G.m.b.H., Germany), nickel-titanium alloy or any combination of biomaterial. For use in the inner ear, the micro-valve **101** may be anchored on the cochlea promontory bone **107.** Similarly, the micro-valve may be located in the round window or semicircular canal of the inner ear. The anchoring and sealing between the metallic and/or polymer based micro-valve **101** and the promontory bone **107** is accomplished through use of, for example, a biocompatible cement, and/or a mechanical fitting in a treaded shaft, and by osteo-integration. The connection between the micro-valve **101** and the promontory bone **107** may be, for example, through a tube with an inner and outer thread. The micro-valve **101** may be removable from the promontory bone **107** if and when necessary.

The placement of the micro-valve **101** typically, but not necessarily, requires drilling a hole approximately .8 to 2 mm or more in diameter on the promontory bone. The micro-valve **101** may be self closing, as shown in Fig. 10, when no fluid pressure is sensed through the catheter, reservoir or pump. The micro-valve **101** may be surface coated, or treated by chemical vapor deposition or other means to prevent tissue growth and occlusion of the valve orifice over time in the intra-cochlea region. The micro-valve **101** may also include a magnet, and a magnetic control system through a tympanoplasty.

Fluid delivery to the micro-valve **101** may be accomplished through a flexible catheter **109** that may be, but is not limited to, .5 to 2 mm in inner diameter. One end of the catheter **109** may be securely connected, for example, to the middle ear side **105** of the micro-valve **101.** The connection is sufficiently tight to prevent fluid leakage from the catheter to the middle ear. The connection may be permanent or dis-connectable through a surgical approach. The catheter **109** inner surface may be treated to impart hydrophillic properties to the lumen, as hydrophillic properties are favorable to the delivery of viscous fluid.

The other end of the catheter may be connected to a fluid source such as a pump **111** with reservoir **113**. Similarly, the fluid source may comprise a reservoir **401** with a passive unloading system such as a spring activated piston or a piston which includes a magnet and is operated by magnetic forces from the exterior or interior as shown in Fig. 4. The catheter **109** may also be connected to an osmotic pump. The pump **111** may be active, which means it may be operated by energy transferred transcutaneously to an electronic control box such as the one used with a cochlear implant or other implantable prosthesis. The pump **111** may also be passive with energy transfer by, for example, a gas or other fluid loaded in a chamber of the pump.

When energy is delivered to the pump **111** to move fluid from the reservoir **113** down the catheter to the inner ear or when the fluid is moved via a spring loaded reservoir **401**, the pressure is sufficient to open the micro-valve **101**. When no energy or pressure is sensed by the micro-valve **101**, the micro-valve **101** may close automatically, thereby sealing the inner from the middle ear. The micro-valve **101** closure may take place through the use of a titanium sphere **1001** attached to a spring **1003** on the inner ear side of the valve as shown in Fig. 10. However, other methodologies for opening and closing the micro-valve **101**, such as fluid pressure or piezoelectrics, may be used.

In another with another embodiment of the invention, the micro-valve **101** may be securely connected directly to a screw-on canister **601** as shown in Fig. 6. This allows for one-time fluid delivery. The canister **601** may be removed and refilled or replaced by another canister with a passive fluid delivery function.

As noted above, fluid delivery systems in accordance with the invention may be used in combination with an electronic prosthesis or implant, for example, a cochlear implant. This may be accomplished in two ways: fusion of the catheter and an electrode associated with the prosthesis or implant, or parallel delivery of fluid and electrical current to the body. Fig. 2 is a graphical illustration of a fluid delivery system fused to a cochlear implant in accordance with an embodiment of the invention. A catheter **109** of the fluid delivery system is connected to a cochlear implant **201** via its electrode **203.** The electrode **203** is hollow over a length which starts at a catheter and electrode junction **205.** (Note that a valve as described above may also be used with this embodiment.) The hollow part of the electrode **203** may continue in length to somewhere intra-cochlea. The hollow electrode **203** acts as a pathway for fluid delivery to the inner ear. On the intra-cochlea section of the electrode one or several channels of adequate size built in the electrode **203** material permit access to the fluid of the inner ear. The catheter **109** which connects a fluid

source to the implant may or may not be dis-connectable from the electrode **203**. When not dis-connectable, a valve or switch (not shown) prevents any connection between the inner ear and the other structures of the temporal bone, including the middle ear (fluid, tissue or air).

Fig. 3 is a graphical illustration of a fluid delivery system implanted parallel to a cochlear implant in accordance with an embodiment of the invention. Parallel delivery means that the cochlear implant **301** and the fluid delivery system **305** are not fused. A single large cochleostomy or two separate but adjacent cochleostomies may be used to accommodate the separate leads of the electrode **303** and the fluid delivery system **305**. The cochleostomy (ies) may be next to each other on the promontory bone. In this case the cochlear implant electrode **303** and fluid delivery system **305** may be introduced in the inner ear through the classical surgery which includes a posterior tympanatomy or one enlarged cochleostomy allowing both electrode and fluid delivery through the same or adjacent promontory bone opening. A typical approach requires that two cochleostomies be drilled after two separate surgical approaches to the promontory bone. The first surgical approach is the classical posterior tympanatomy. The second surgical approach is a variant of the so-called supra-meatal approach that has been described by Prof. Kronenberg, Prof. Häusler, and Dr. Kiratzidis. The electrode or fluid delivery system may be inserted in the classic cochleostomy following posterior tympanotomy. The electrode or fluid delivery system may be inserted in a cochleostomy following the suprameatal approach. The electrode or fluid delivery system may also be implanted through the round window. All permutations of electrode and fluid delivery system are possible with the two cochlestomies or one cochleostomy and the round window opening.

Fig. 5 is a graphical illustration of a fluid delivery system in accordance with another embodiment of the invention. In accordance with this embodiment, the catheter may be inserted directly in the inner ear without a promontory valve present. In this case a cochleostomy is drilled and the catheter is inserted a certain distance in the opening. The catheter may be securely sealed with fibrin glue (for example) on the promontory bone.

Fig. 7 is a graphical illustration of a switch that may be implanted under the skin in accordance with embodiments of the invention. In the various embodiments (reservoir with piston, reservoir and pump, screw on canister, refillable and non refillable reservoir, reservoir incorporated with a cochlear implant system, drug delivery system with or without valve on the promontory, etc.) a provision may be incorporated to stop fluid flow at any time during fluid delivery if the patient should suffer side effect. Fluid flow may be

stopped, for example, through telemetry when a pump with a telemetry receiver is included in the design. Fluid may also be stopped by a passive on/off mechanical switch **701**. Such an on/off switch **701** may be incorporated on the catheter, on the reservoir, or on the valve, for example. The switch **701** may be activated on or off manually when reachable from the outside (if located at the surface of the skull just underneath the skin for example). The switch **701** may also be activated through a magnetic energy transmitted transcutaneously or through the tympanic membrane **801**, shown in Fig. 8. The switch may also be activated on or off through a small opening on the tympanic membrane (tympanoplasty) followed by insertion of a specially designed tool in the valve or on a specially located switch in the middle ear close to the valve. The specially located switch may be a metallic part overhanging the promontory and accessible through a tympanoplasty.

In accordance with various embodiments of the drug delivery system, the reservoir or canister may be refillable. Fig. 9 illustrates that refilling may take place, for example, through injection of the therapeutic fluid through a thick impermeable membrane located on top of the reservoir, or through a special outlet valve. Such refilling can take place following a local anesthesia, and after incision of the skin covering the reservoir. Refilling may also take place through a small incision on the tympanic membrane and the introduction of a needle in a receptacle on the reservoir. When the delivery system is a spring loaded reservoir, for example, a valve switch system may be used to refill the reservoir. After access to the apparatus, valve switch **901** is closed and valve switch **902** is open. Fluid may be injected through the switch valve **902** with a needle for example, thereby pushing piston **903** back and loading the pump fluid and compressing the spring **905**.

Fig. 11 is a graphical illustration of a fluid delivery system for delivery of fluid through the tympanic membrane of a subject. Here, the pump and/or reservoir **111, 113** is located outside the outer ear, and a catheter traverses the outer ear and the tympanic membrane. A segment of the catheter **1101** in the middle ear connects to a valve located on the promontory bone, round window or oval window. The catheter **1101** connection may be dis-connectable by pulling back on the catheter tube and causing a force from the middle ear toward the outer ear. As in the embodiments described above, the pump/reservoir may comprise and on/off switch and the reservoir may be refillable.

Figs. 12-14 illustrate another device for delivering fluid to the body of a subject. The device includes a fluid source, such as a fluid pump **1201** (as shown in Fig. 12) or a fluid port or fluid reservoir **1301** (as shown in Fig. 13). The device further includes a

microseptum connector **1203**. The micro-septum connector is in fluid communication with a spear catheter **1205** at a proximal end which, in turn, is in fluid communication with the fluid source. The micro-septum connector **1203** is also in fluid communication with a port catheter **1207** at a distal end. The port catheter **1207** may be in fluid communication with another catheter (not shown) or with one or more electrodes or electronic prostheses **1401**, as shown in Fig. 14. Each electrode or electronic prostheses **1401** may have one or more fluid channels **1403** with outlets such that each electrode or electronic prosthesis **1401** acts in part as a catheter having one or more outlets.

As described above, the micro-septum connector **1203** is in fluid communication with an implantable fluid pump, a fluid port or reservoir, or an osmotic pump via a spear catheter **1205** and in fluid communication with the body of the subject via a port catheter **1207** which may be connected to or in fluid communication with another catheter or an electrode or electronic prosthesis (such as **1401**). The fluid delivery device (such as the port catheter **1207** and electrode or electronic prostheses **1401**) and the device that drives and delivers the fluid (such as the fluid pump **1201** or fluid port **1301**) are designed to be implanted in a human subject or an animal subject in the course of a surgical procedure. The connection between the two devices is accomplished with the micro-septum connector **1203**.

Fig. 15 is a graphical illustration of a micro-septum connector according to an embodiment of the invention. The micro-septum connector comprises an implantable port connector **1501** and an implantable spear connector **1503** (shown unconnected in Fig. 15 and connected in Fig. 16). The implantable port connector **1501** includes a septum **1505** and may be in fluid communication with the port catheter **1207** which transports fluid to a specific location in the subject's body at its distal end. (When in fluid communication with the port catheter **1207**, the port connector **1501** is located at the proximal end of the port catheter **1207** as shown if Figs 12-14.) The distal end of the port catheter **1207** may have one or more openings to allow fluid to disseminate in the surrounding biological tissue. The spear connector **1503** includes a needle **1507** and may be in fluid communication with the spear catheter **1205** at its distal end. Toward the proximal end of the spear catheter **1205** a fluid source is attached.

In one embodiment of the invention, the proximal end of the port connector **1501** and distal end of the spear connector **1503** do not join surface to surface. This is to prevent the creation of dead space between the flat surfaces of the micro-septum connector **1203** when joining the port connector **1501** and spear connector **1503** via the needle **1507**. In

such an embodiment, the needle **1507** of the spear connector **1503** traverses the septum **1505**, but a remaining part of the needle **1507**, anterior to the septum **1505**, is exposed to body fluid and body tissue. Such a situation promotes a good tissue seal at the point where the needle **1507** enters the septum **1505**. In addition, the encapsulating tissue is irrigated by the surrounding tissue and can respond well to any inflammation. It is also feasible to introduce tissue, fascia or muscle through the needle **1507** up to the flat end of the spear connector **1503**. Introduction of tissue will promote good healthy tissue growth between the flat ends of the port connector **1501** and spear connector **1503**. As can be seen in Fig. 16, once joined, the port connector **1501** and the spear connector **1503** permit safe fluid transport without leakage to the surrounding biological environment.

An important feature of the port connector **1501** is the septum **1505**. The septum **1505** is made preferably of rubber silicone. The port connector **1501** may also include a compression ring **1511**. The compression ring **1511** (or other compression device) compresses the silicone to impart septum properties to the device. The compression ring **1511** is preferably made of medical grade titanium, however, any other material that can compress the silicone in a cylindrical part may be used. Such materials may include shape memory nitinol metal and memory shape polymer. The compression ring **1511** may be terminated toward the connecting side of the port connector **1501** by a guide or a guide mechanism **1513**, stopper or other stopping device **1515** and locking mechanism **1517**. A bacterial filter **1509** may or may not be placed between the port connector **1501** and the port catheter **1207**. The port connector **1501** may also include a reservoir **1521** which may be lined with titanium shell or a titanium shell to prevent piercing by the needle **1507**. The proximal end of the port catheter **1207** may optionally be silicone bonded with the port connector. A layer of silicone may be deposited on the entire port connector **1501** to prevent exposure of metal to the environment, and favor encapsulation. Deposition may be accomplished by dip coating the port connector **1501** in the appropriate silicone rubber solution.

The spear connector **1503** may be made of silicone or epoxy or any other bio compatible material as deemed necessary or profitable to the invention. A medical needle (such as **1507**) of appropriate size, material, and shape is inserted in a mold such that both ends of the needle protrude out of the mold. Injection molding of silicone and/or medical grade epoxy solidly encases the core of the needle. A catheter (such as the spear catheter **1205**) is introduced on one end of the needle and silicone is added and cured to seal the spear connector. The needle **1507** may be slanted and sharp on the side that will pierce the

septum **1505**. Note that the hole on the needle **1507** that will transfer fluid may be at the end of the needle or may be on the side of the needle at a short distance from the tip.

As noted above, the micro-septum connector **1203** may also include a guide or guiding mechanism (such as **1513**) to line up the needle **1507** and the port connector **1501** before piercing of the septum **1505** by the needle **1507**. The guide or guiding mechanism **1513** permits the lining up of the tip of the needle **1507** with the center of the septum **1505**. The guide or guiding mechanism **1513** also prevents large deviation of the needle **1507** upward or downward or sideways. Such deviation could lodge the tip of the needle **1507** in the internal wall of the port connector **1501** and prevent fluid flow.

The stopper or stopping device **1515** may be used to prevent the fusion of the spear connector **1503** and the port connector **1501** on their flat surfaces. The stopper or stopping device **1515** permits a section of the needle **1507** to be exposed to the body fluid even at full insertion. The stopper or stopping device **1515** consequently prevents the creation of a dead space between the flat surfaces of the implantable port and spear connector ends when connected (unless such a flat connection is profitable to the invention by, for example, having an antibiotic coating to prevent formation of a nidus of infection at all time).

The locking mechanism **1517** may be included in the micro-septum connector **1203** to promote the stability of the micro-septum connector **1203** under normal body movement and usage stress. The locking mechanism **1517** may be reversible to allow for replacement of one or more of the parts described above.

Once fabricated and sterilized by appropriate means, a surgeon may join the port connector **1501** and the spear connector **1503** by introducing the needle **1507** through the septum **1505** and, optionally, locking the micro-septum connector **1203** with the locking mechanism **1517**. Before joining the port connector **1501** to the spear connector **1503**, each may be filled separately with a fluidic pharmaceutical agent. Separate filling allows good priming of the implantable connectors **1501** and **1503** before connection. Filling of the spear catheter **1205** may be accomplished by filling the pump (usually though a pump septum), port with septum and reservoir, or osmotic pump. It may also be that the implantable connectors **1501** and **1503** are connected before any filling and priming of the devices takes place.

If removal and replacement of one or both of the implantable connectors **1501** and **1503** is desired, surgical intervention may include careful removal of tissue growth and membrane encapsulation around the port connector **1501** and removal of the spear connector **1503** by pulling back on one or the other connectors. At this stage either or both

of the port connector **1501** and spear connector **1503** may be positioned in the biological environment of interest. This may be done after priming the system in the usual fashion described above. Once replaced and positioned, connection of the port and spear to connectors is accomplished by engaging the port connector **1501** and spear connector **1503** (perhaps by employing the guide **1513**), piercing the septum **1505**, and, if desired, locking the mechanisms via the locking mechanism **1517.**

The system described with respect to Figs. 12-16 may be used to provide fluid to the inner ear of a subject. Fig. 17 is a graphical illustration of an apparatus for delivering fluid to the inner ear of a subject in accordance with a further embodiment of the invention. The inner ear comprises the cochlea and the semi circular canals (not shown). Fluid delivery may be accomplished through an electrode of a cochlear implant, if so desired, or through a reinforced fluid delivery catheter for partial and full insertion into the inner ear, or through a catheter just apposed against the round window membrane. When such an application is desired, a bony recess may be formed on the surface of the skull to partially bury the connector assembly. Burying the connector prevents protrusion of the connector under the scalp.

In accordance with the embodiment of Fig. 17, a spear connector **1205** and needle **1507** are used to provide fluid to a septum **1701.** The septum **1701** may be of appropriate size and shape to be embedded in the inner ear of a subject or on the promontory bone **1703** following surgery. A metal flap or a facial recess may be employed as a bone fixation feature **1705** in order to fix the septum **1701** to the inner ear or the promontory bone **1703.** For example, after drilling the promontory bone **1703** with a 2 mm or smaller bore, a conical bed may be made in the bone. A simple conical septum (such as **1701**) may be lodged at the opening of the cochlea canal **1708** and anchored on the promontory bone **1703** of the cochlea. The septum **1701** will then remain available for fluid delivery via connection with the spear connector **1205.** In such a configuration, the semi circular canal (including the utricule) may be accessible for fluid delivery. Additionally, the configuration of Fig. 17 may also include a compression ring **1707** and stopper **1709** for the purposes explained with respect to the embodiments above.

The fluid delivery systems of Figs. 12-17 can be easily and quickly connected with a connector. Connections may be long term and leak proof and the fluid delivery systems can be easily disconnected. Upon disconnection, the port catheter may remained sealed, and the fluid delivery systems may be reconnected with a different or with the same fluid driver. The port catheter may remain implanted for use years later while the driver is

explanted. If the device is used with an electrode, the electrode does not need to be removed if the fluid driver is taken out. In addition the fluid driver may be reconnected to the electrode at a later date. Fluid delivery modules may be connected in parallel to a single port catheter if so deigned.

Figs. 18 and 19 illustrate a catheter in accordance with another embodiment of the invention. The catheter **1801** is designed to be partially or fully inserted in the body of a subject. For example, the catheter **1801** may be inserted in the inner ear (scala tympani, scala vestibuli, or semi circular canals) through a cochleostomy and to deliver pharmaceutical agents to the fluid of the inner ear. Atraumatic insertion of the catheter **1801** depends on the mechanical properties of the catheter. Mechanical properties must be such that an atraumatic insertion around the curvature of the scalae is possible.

The catheter **1801** may be conical or cylindrical in shape, round or elliptical in cross section and may have a rounded tip **1811** for ease of implantation. The catheter **1801** may be polymer based, and the polymer may include silicone, for good flexibility. Alternatively, the catheter may be made of a biodegradable polymer. Similarly, the catheter **1801** may be made of a material which shrinks when stretched.

The catheter **1801** may optionally include one or more reinforcing wires and/or ribbons **1807** made of hard polymer filament or metal or metal alloy to increase the pushability of the device and enhance implantation. The catheter **1801** may also include markers **1805** on the surface of the polymer to indicate insertion depth and/or an adjustable blocker to close the cochleostomy through which it is inserted. Embodiments of the catheter **1801** include double outlets **1809** to provide free flow in the fluid, and these outlets **1809** may be in opposite directions. Similarly, the catheter **1801** may include more than one channel **1803, 1817, 1819** in the center (or toward edges) of the catheter body to control a fluid or drug concentration-distribution profile. The catheter **1801** may also include a lubricating coating to enhance insertion. Similarly, the catheter **1801** may be coated with cortico steroid and/or antibiotics to prevent infection.

In related embodiments, the catheter **1801** may have an on/off switch or valve **1813** accessible by the subject (activated by a magnet or by mechanical pressure) located on the subject's body such as on the skin or, when used in connection with fluid delivery to the inner ear, on the skull between the fluid delivery reservoir and intra inner ear section. The valve or switch **1813** may be used to prevent backflow of fluid. The catheter **1801** may additionally include a moveable stopper **1815** to promote ease and accuracy of insertion.

The catheter **1801** is designed with an internal channel **1803** for fluid delivery. For example, localized delivery of fluid to the inner ear may maintain spiral ganglions cell functional characteristics, regenerate dendrites, and promote the preservation of residual hearing, arrest progressive hearing loss. Applications may include delivery of cortico-steroids to prevent inflammation, medicine to arrest sclerosis, and tissue growth and be used for the novel treatment for tinnitus and vertigo.

Fluid delivery is accomplished through the hollow channel **1803** formed on the catheter lead up to a location intra scala. One or more outlets **1809** may be included in the catheter **1801**. The channel **1803** may be connected to an internal micro pump or to a port including a septum for external pumping of pharmacological agent. The hollow channel **1803** disposed close to the center or more off-centered to the edges of the catheter **1801** is formed by reverse molding. This means that a place holder may be included in a mold prior to injection molding. After injection molding, the place holder then is removed and a hollow channel is left in its place. Outlet(s) **1809** for the fluid delivery channel may be located basally and/or apically. The outlet(s) **1809** for fluid delivery may be coated with a ring of slow release bioactive agent to prevent tissue growth and occlusion of the outlets over time.

Each single outlet **1809** for fluid delivery may include two outlet channels **1817** and **1819** 180 degrees apart. The two outlet channels **1817** and **1819** are connected either in a rectilinear fashion or they are offset from one another The object of having the two outlet channels 180 degrees apart in a catheter designed for fluid delivery to the inner ear (as shown in Fig. 19) is to ensure that one outlet channel is always facing the perilympahtic fluid. With one outlet channel of the outlet **1809** facing the basilar membrane or the lateral wall of the scala tympani the possibility of the outlet channel becoming occluded exists. Each outlet channel may be formed with micromachined titanium and the metal laced with Cortico steroid-laced Silicone (drug eluting) covering (conformal coating, dipped, plasma deposition) on titanium micro tube. Such surface modification is intended to prevent occlusion of the outlets **1809**.

Fig. 20 is a graphical illustration of an implantable electrode in accordance with another embodiment of the invention. The electrode **2000** comprises an electrode lead **2001** and an electrode array **2003**. The electrode array **2003** includes a front end **2007** and a back end **2005**. The electrode array **2003** is defined as the distance from the first contact **2009** on the front end **2007** to the last contact on the back end **2005**. The electrode **2000** is

made of a polymer with wires and contacts **2009** embedded or deposited on the polymer. The polymer may be silicone, fluoropolymer, or other biocompatible material.

Most cochlear implant electrodes which have been designed for scala tympani lateral wall placement have a limited electrode extent of around 16 mm. Insertion depth of the electrode in the scala tympani is usually limited to around 23 mm. An electrode extent of 16 mm inserted 23 mm along the lateral wall of the scala tympani covers a limited sound frequency range and bandwidth in the cochlea. With the electrode partially displaced towards the medial wall, the frequency range increases but remains fractional of the full bandwidth since some electrodes are more or less close to the lateral wall. With an electrode extent of more than 26 mm inserted 28 to 31 mm along the outer wall the near complete bandwidth of the cochlear can be stimulated either at the spiral ganglion cells in the first cochlea turn, and/or at the axonal processes in the 2nd turn. With deep insertion, current spread is not required for stimulating tonotopic regions out of range of the 1st and last contact on the electrode array. A prerequisite to the benefits associated with deep electrode insertion is minimum insertion trauma from base to apex.

The electrode **2000** is designed to have properties which reduce the amount of force necessary for introduction in the cochlea. Reducing the electrode insertion force and increasing the electrode flexibility reduces the amount of trauma inflicted to the soft tissue which lines the scala tympani walls. Reducing the insertion trauma to the maximum is most beneficial to the patients who suffer from severe deafness and may be using a hearing aid in the ipsilateral ear, or have residual hearing which allows perception of low frequency sound unaided but have poor speech discrimination. The interest in keeping electrode trauma minimized is compounded by the fact that a patient implanted today may receive a device replacement or a device addition which restores some aspects of the degenerated neural pathway. If such neural a pathway is mechanically disturbed during electrode insertion there is a high likelihood that the pathway will be permanently destroyed.

A cochlear implant electrode is usually inserted through the inner ear (scala tymapani or scala vestibuli) through a hole drilled on the bony surface protecting the spiraling cochlea. If residual hearing is present it may be of interest to limit the insertion depth to a region below where acoustic hearing is present. A stopper **2015** on the electrode **2000** can limit insertion depth to a fixed predetermined value, 20 mm for example (but not limited to 20 mm) 20 mm corresponds to about 1 turn of cochlea. The stopper **2015** is designed to have vertical wall which prevents insertion beyond the cochleostomy. Slots may be built on the stopper **2015** to allow a surgeon to view the cochleostomy as the

stopper **2015** approaches the external bone of the inner ear. In another embodiment, the stopper **2015** has a conical shape which allows for plugging of the cochleostomy. The stopper **2015** can also be a slider which is moved down from a superior region on the electrode **2000**.

The insertion depth of the electrode **2000** may be controlled and limited to a pre-determined value. The pre-determined insertion depth value may be based on the patient audiogram. If the audiogram indicates significant residual hearing (50 dB or more for example) up to 2000 Hz, the surgeon could choose to limit insertion depth to 16 mm. The limitation of the insertion depth may take place with the use of a pre-cut biocompatible and sterile tube inserted from the from end of the electrode down to the stopper **2015.** A 4 mm long tubing of sufficient thickness in front of a 24 mm long electrode (length from electrode tip to stopper wall) would limit insertion depth to 20 mm.

What distinguishes the electrode **2000** from other designs is the presence of the front end **2007** and back end **2005** on the electrode array **2003**. The front end **2007** is much thinner than the back end **2005**. In one embodiment, the front end **2007** of the electrode **2000** covers 1/4 to 1/2 of the electrode extent. The bulk mass of front end **2007** of the electrode **2000** may be about 1/2 the bulk mass of the back end. It is understood that in this design the electrode **2000** neither grows continuously, nor is of constant diameter or cross sectional shape along the electrode extent. Rather, the electrode **2000** includes a discontinuity in its cross sectional shape. The discontinuity defines the limit of front end **2007** and the beginning of the back end **2005** of the electrode array **2003**. The front end **2007** is designed to have low insertion and low bending forces required to push the array around the coiling, upward spiral geometry of the scala tympani. The back end **2005** is designed to maximize the pushability of the electrode to achieve a deep insertion when required. Pushability is important for electrode design since an electrode with low pushability will collapse around the cochleostomy before able to impart a forward movement to the tip **2011** of the electrode. To favor the insertion of the electrode **2000**, the tip **2011** of the device may be thin and rounded with no sharp edges. In addition the front end **2007** and the back end **2005** of the electrode array **2003** may be tapered. Tapered in this sense means that the cross sectional area of the front end **2007** and back end **2005** grows continuously.

On the electrode extent, eight or more contacts **2009** are embedded or deposited on the polymer substrate. At present, eight contacts **2009** are the minimum required to reach asymptotic performance in speech understanding for implanted patients. The contacts **2009**

may be made of platinum (Pt), platinum iridium (PtIr), or iridium oxide. The contacts **2009** may be round or oval or may be rectangular shaped with rounded edges. Rounded edges reduce the current density at the edges of the electrode contact. Current density at the edge of the contact **2009** surface is usually responsible for the initial contact dissolution of the metallic surface. The contacts **2009** may be in the form of a spherical ball such as that produced by flaming the tip of a platinum iridium wire. Each of the contacts **2009** may be a single or paired contact. In one embodiment, a combination of paired and single contacts may be used. Contacts **2009** located on the back end **2005** are paired while contacts located on the front end **2007** are unpaired. In this manner the flexibility of the front end **2007** of the electrode is preserved while the pushability of the back end **2005** is maintained.

Each contact **2009** is electrically connected to an insulated wire (**2201, 2203, 2205,** or **2207,** shown in Fig. 22) that runs through the polymer matrix forming the electrode **2000**. The electrode wires **2201, 2203, 2205,** or **2207** are thin down to 15 microns in diameter as thin wires reduce the insertion force. The wires **2201, 2203, 2205,** or **2207** are preferably wiggled as shown in Fig. 22. Wiggled wires are much more flexible than straight wires and they require much less force to bend. The frequency and magnitude, and shape of the wiggled wires is adapted to minimize insertion forces.

Fig. 23 is a graphical illustration of an implantable electrode array for delivering fluid to the body of a subject in accordance with another embodiment of the invention. In accordance with this embodiment, an implantable electrode **2300** is designed with an internal channel **2301** for fluid delivery. For example, localized delivery of fluids to the inner ear in the presence of a cochlear implant electrode (see Fig. 24) could maintain spiral ganglions cell count as well as functional characteristics, regenerate dendrites, and promote the preservation of residual hearing. Applications could include delivery of cortico-steroids to prevent inflammation and intra scala tissue growth as well as novel treatment for tinnitus and vertigo. The inclusion of a fluid delivery function with a cochlear implant is therefore a valuable aspect of cochlear implant design.

Fluid delivery is applied through a hollow channel **2301** formed on the electrode lead up to a location intra scala. One to several outlets **2307** may be included between or close to the electrode contacts **2309**. The hollow channel **2301** may be connected to an internal micro pump or to a port including a septum for external pumping of pharmacological agent. The micro pump or the port may be located near the implant housing. The method for fabricating the hollow channel **2301** such that it is close to the center or more excentered to the edges of the electrode **2300** includes reverse molding.

Again, in reverse molding, to form an internal hollow channel **2301**, a place holder is included in the mold prior to injection molding. After injection molding the place holder is removed and a hollow channel is left in its place.

One or more outlets **2307** for the fluid delivery channel **2301** may be located near or in between basal contacts **2309** located on the electrode array **2303**. The outlet(s) **2307** for fluid delivery may be coated with a ring of bioactive agent to prevent tissue growth and occlusion of the outlets over time.

Fig. 25 is a graphical illustration of the fluid delivery outlets of the electrode array of Fig. 23. Each single outlet **2307** for fluid delivery includes of two outlet channels **2317** and **2319** 180 degrees apart. The two outlet channels **2317** and **2319** are connected either in a rectilinear fashion or they are offset but in each case they are 180 degrees apart. The object of having the two outlet channels **2317** and **2319** 180 degrees apart in a electrode for a cochlear implant is to ensure that one outlet channel is always facing the perilymphatic fluid. With one outlet channel of the outlet **2307** facing the basilar membrane or the lateral wall of the scala tympani the possibility of the outlet channel becoming occluded exists. The fluid delivery outlets **2307** may be made of titanium or other metal coated with a pharmaceutical agent, including lubricating coating to prevent occlusion of the openings when the drug is not pumped through the channel **2301**. The coated fluid delivery outlets **2307** are embedded into the silicone of the electrode.

Fig. 26 is a graphical illustration of an electrode for use in connection with an implantable prosthesis in accordance with a further embodiment of the invention. In accordance with this embodiment, the implant electrode **2600** includes an electrode array **2613** and an electrode lead **2611**. The electrode lead **2611** is to be electrically connected to a metal or ceramic housing **2601** containing electronics. The electronics generate a current pulse to be delivered to the electrode contacts. The current pulse travels to the contacts via wires embedded in a polymer matrix. The electrode lead **2611** may optionally be terminated at a right angle.

Modeling of intra cochlear stimulation and animal EABR data indicates that an electrode array positioned close to the inner wall of the scala tympani would be beneficial to the neuro stimulation of cochlea implants. Such electrodes are referred to as perimodiolar electrode. There is a consensus that a perimodiolar electrode would lower psycho-acoustic threshold, increase the dynamic range of stimulation, and reduce channel interaction. Channel interaction may be caused by the field overlap from individual electrodes. Further potential benefits expected from a perimodiolar array include reduced

power consumption to drive the implant, reduced side effects for the patient, implementation of innovative stimulation scheme, and better place coding of frequency. A larger number of electrodes may be effectively used.

Figs. 27-30 illustrate of an implantable electrode array in accordance with another embodiment of the invention. In accordance with this embodiment, the electrode is designed to be displaced toward the inner wall of the scala tympani upward spiraling cavity as shown if Fig. 29. The front end **2707** of the electrode **2700** is unchanged from that described in accordance with Fig. 23. The front end **2707** of the electrode **2700** facilitates deep penetration of the scala tympani with minimum insertion forces. The back end **2705** of the electrode, however, is modified. The back end **2705** of the electrode **2700** is segmented in two parts that are joined together for insertion. After full insertion of the electrode **2700**, the two segments **2711** and **2713** situated on the back end **2705** of the electrode array are disconnected by a pull back movement on the segment which comprises the electrode. In this embodiment, the two segments **2711** and **2713** remain connected at the junction of the front end **2707** and back end **2705** of the electrode **2700**. When used with a cochlear implant, the two segments **2711** and **2713** also remain connected in a location in the middle ear. The two segments **2711** and **2713** are disconnected in between the two mentioned locations.

For clarity the two segments are referred to as the electrode branch **2713** and a restraining arm **2711**. The two segments **2711** and **2713** are and remain connected during the whole insertion process. The preferred method of connecting the segments is via the pressure mating of a rail molded on the electrode branch **2713** with a slot molded on the restraining arm **2711**. In a cochlear implant, segments **2711** and **2713** are latter disconnected for the positioning of a section of the electrode branch against or close to the modiolus. The cochlea from a human temporal bone with the electrode and restraining arm in position is shown on Figure 29.

The restraining arm **2711** may include in its mass and along its whole length a platinum (Pt) or a platinum iridium (PtIr) ribbon or wire **2715**, annealed or not annealed, to increases or decrease the rigidity of the restraining arm. Such control of the rigidity of the restraining arm **2711** is important in a cochlear implant to maintain good insertion properties (flexibility) as well as sufficient rigidity for when a retro positioning technique is applied to the electrode branch **2713** to displace the electrode branch **2713** closer to the modiolus. If the restraining arm **2711** is too soft, it will buckle during the retro-positioning technique.

The shape of the ribbon **2715** may be that of a rectangle with a ratio of length to width of 2 to 1 (as shown in Fig. 28). The orientation of the ribbon **2715** may be such that the shorter length oriented medial to lateral (from outer wall-inner wall). Such an orientation of the ribbon **2715** in a cochlear implant facilitates the movement of the electrode array **2703** from the base of the scala toward the apex, while reducing movement of the array in the superior direction, toward the fragile tissue of the basilar membrane and organ of Corti. An added advantage of the rectangular shape of the ribbon **2715** is that it maintains the electrode contact facing the modiolus during insertion. The generally rectangular shape of the PtIr ribbon **2715** may have rounded angles to reduce any cutting into the silicone matrix, which form the restraining arm **2711**. The metallic core of the restraining arm **2711** may be modified in all or in parts to increase flexibility or rigidity of the restraining arm **2711** in whole or in part as is deemed necessary to the invention. Modification of the ribbon **2715** may include but is not limited to, heat, chemical, and mechanical treatment of the metal. It is understood that the composition of the restraining arm **2711** is not limited to a combination of silicone and metal, and that other biocompatible polymer such as Teflon may be used in connection with the restraining arm concept.

When used with a cochlear implant, the electrode **2700** may be sequentially inserted, and then the electrode **2700** is positioned toward the inner wall. In a first phase, the electrode array **2703** with the two segments **2711** and **2713** connected is inserted along the outer wall of the scala tympani. In a second phase, the section of the back end **2705** of the electrode array **2703** corresponding preferably to the basal turn of the scala tympani is displaced to come close to or to connect with the inner wall of the same scala tympani. This section is now referred to as the perimodiolar section. The perimodiolar section corresponds preferably to the basal turn of the cochlear because this is where the majority of electro-excitable neural elements are situated. These neural elements (spiral ganglion cells) would benefit the most from more proximal electrode stimulation. The remaining intra cochlear section of the electrode branch **2713** is referred to as the deep insertion section. The deep insertion section is designed to be deeply inserted in the scala tympani but it is not positioned against the inner wall by any voluntary action.

Following the full insertion of the segmented electrode array **2703** into the scala tympani of the cochlea, the restraining arm **2711** is held stationary posterior to the cochleostomy (outside the cochlea) by the surgeon and with some micro-tool such as forceps or tweezers. The electrode branch **2713** is then unmated or disconnected from the

restraining arm and retracted out of the scala. This slight pulling of the electrode array **2703** out of the cochlea effectively uncouples the electrode branch **2713** and the restraining arm **2711**, except at the point where the two segments converge. It is important to note that at the convergence point the two segments are attached via a metallic rod or ribbon **2715** made of PtIr 80-20%, for example, such as that supplied by Medwire Sigmund Cohn Corp, Mount Vernon, NY. In one embodiment, the end of the wire or ribbon **2715** fits into a silicone hollow cavity on the electrode branch **2713**. Key to the retro-positioning technique is the synergy between the less flexible ribbon **2715** and wire in the core of the restraining arm **2711** and the more flexible electrode branch **2713**.

An important element of the electrode **2700** is the segmented aspect of the electrode. Another substantial element of the design is the option to connect firmly the two segments **2711** and **2713** for ease of insertion. The firm and yet detachable connection may be established by several means. One means of segment connection is via a rail and a slot having matching dimensions. The electrode branch **2713** and restraining arm **2711** may be pressure mated during manufacturing. The mating of the silicone keeps the electrode and restraining arm connected during insertion.

Another means of connecting the two segments **2711** and **2713** is via an envelope design. If such a design is adopted, the envelope may be round or ellipsoid in shape. It is understood that the mating of the electrode is not restricted to the designs shown and that any mating which is profitable for the connection, insertion, disconnection, and positioning of the electrode is feasible. In accordance with yet another method, the two segments **2711** and **2713** may be connected with a hydrogel which dissolves in the fluid of the inner ear within a few minutes of insertion. The binding of two dissimilar silicones which are dis-connectable may also connect the two segments.

The electrode segments **2711** and **2713** have a convergence point so that when the implant needs replacement, the two segments **2711** and **2713** of the electrode array **2703** should be easily dis-connectable. In order to achieve dis-connectability as well as restraining action during retro-positioning, the two segments **2711** and **2713** may be joined by a bare PtIr ribbon **2715** section, which comes out of the restraining arm **2711** and is lodged snugly or loosely in an oriented silicone cavity molded on the electrode branch **2713**. In case of revision surgery, the two segments **2711** and **2713** can be dislocated at their point of convergence by pulling back on the restraining arm **2711** with sufficient force. The cavity may be parallel to the axis of the array or may be oriented in such a way

as to provide resistance for retro-positioning. The ribbon or wire **2715**, which is used as the spine of the restraining arm **2711**, may be terminated as a ball to reduce sharp edges.

The two segments **2711** and **2713** of the electrode array **2703** may be attached together outside the cochlea. Such attachment may be advantageous to prevent the movement of the electrode branch **2713** in relation to the restraining arm **2711**. With respect to a cochlear implant, movement of the electrode branch **2713** post-operatively could lead to a release of the connection of the electrode branch **2713** with the modiolus. The in such an embodiment, the two segments **2711** and **2713** may be attached with a closable titanium clip **2717** seen more clearly in Fig. 30.

There are several advantages of the electrodes described above. First, in a cochlear implant, a section of the electrode may be deeply inserted in the cochlear, up to the apex, with minimized forces because of the front end design of the electrode. Additionally, a section of the electrode preferably corresponding to the first turn of the cochlear may be displaced toward to and up to the inner wall of the inner ear cavity. The two segments **2711** and **2713** of the electrode are and remain attached during the insertion process (but are disconnected during the positioning process, post insertion, and by voluntary action). The connection to the modiolus is independent of morphology and special tools are not required for insertion and positioning.

The front end **2707** of the electrode **2700**, for up to a 15 mm length, may be coated with a thin biocompatible lubricating coating **2719**. The coating **2719** may be permanent or biodegradable. Lubricating coating reduces the friction between the electrode and the tissue during insertion, therefore reducing insertion forces. Lubricating coating needs to be applied in a restricted front end length of the electrode so that instrument can hold the electrode and push in.

The electrode may also be equipped with a stopper (as show in Figs. 20 and 23) located on the outer shell of the polymer electrode. The stopper **2015** is designed to prevent electrode insertion beyond a defined limit. The defined insertion limit is from 18 mm to 31 mm. The stopper **2015** may be made of a polymer material such as silicone, and preferably of the same material as the electrode. A polymer tube such as silicone can be inserted in front of the stopper **2015** to limit the electrode insertion to a pre-defined limit which may be adapted tot the audiogram of the individual patient. The shape of the stopper **2015** may be such that it allows the surgeon to see beyond the stopper **2015** through slits manufactured on the stopper **2015**. Further, a marker **2721** may be placed on the electrode array **2703** toward the back of the array to indicate the direction of the contact line and to

therefore indicate how to maintain the contact orientation once all contacts **2709** have disappeared in the cochlea.

In yet another embodiment, the implantable electrodes may have an impermeable connector (as at **2313** of Fig. 23 or **2723** of Fig. 27) between the distal and proximal end of the electrode. A connector is desirable since multiple re-implantations are likely to occur during the lifetime of the patient. Re-implantation is usually caused by electronic failures in the housing part of the implant and do not implicate the electrode itself. With respect to cochlear implants, each re-implantation with the removal of the electrode array from the inner ear is likely to inflict some additional damage and trauma to the internal tissue of the inner ear. Since trauma may be cumulative, inner ear function such as spiral ganglion cells and nerve tissue survival may decline over time. The use of an impermeable connector **2313** or **2723** suppresses cumulative trauma due to re-implantation since with a connector re-implantation only requires removal of the implantable electronics when such electronics failed. Such connector **2313** or **2723** is preferably located in the middle ear cavity or in the mastoidectomy. The connector **2313** or **2723** may also be placed on the surface of the skull close to the housing, which contains the encapsulated electronics.

The connector **2313** or **2713** should be impermeable to fluid penetration. The function of impermeability may be brought about by pressure mating of a male and female connector or a flat bed connector. Impermeability may also be imparted by the use of a fast curing elastomer or other synthetic material pasted around the two connector parts. Curing causes sealing of the connector part and insulation from moisture. The connector ideally has as many leads as there are electrode channels. For a cochlear implant, the location of the connector **2313** or **2723** may be in the middle ear, in the mastoidectomy, or on the implant housing.

Fig. 31 is graphical illustration of a further apparatus for delivering fluid to the body of a subject in accordance with a further embodiment of the invention. The apparatus includes a fluid reservoir **3103** with septum **3101** and a catheter **3107**. The apparatus connects the inner surface of the skin of a human or animal subject with a fluid filled non-vascular organ in the human body and permits injection of fluids or pharmaceutical solutions topically to the particular organ though the flexible polymer catheter **3107** which is terminated by a metallic hollow needle **3109** (shown in detail in Fig. 32). The fluid reservoir **3103** and septum **3101** may be driven by an external or by an implantable pump. The apparatus may include a bacterial filter and/or flow restrictor **3105** disposed between the reservoir **3103** and catheter **3107.** In accordance with a related embodiment, the

apparatus may also include a donut or ringed shaped gold covered magnet (not shown) on the inner skin surface of the reservoir **3103** for positioning a needle on top of the septum **3101.** Such a magnet may be encapsulated in a layer of silicone continuous with silicone covering the reservoir **3103.** Further, the inner surface of the catheter **3107** and the exit needle **3109** may be coated with hydrophobic or hydrophillic conformal coating to prevent or restrict fibrous tissue growth and prevent biofilm formation. The exit needle **3109** may have an outlet at its tip or at its sides. Such an apparatus may be connected to the inner ear, the bladder, the stomach, or the intestines of a human or animal subject. When connected to the inner ear of a subject, the needle **3109** may be partially inserted in the posterior tympanotomy or in the mastoidectomy.

As noted above, the reservoir **3103** may be metallic and silicone covered. The reservoir may also be conically shaped and the septum **3101** may be disposed on the greater diameter of the cone. When connected to the inner ear of a subject, such a conically shaped reservoir should be of dimensions adequate to snugly fit in a mastoidectomy, such that the non-septum side of the reservoir **3103** is connected to a catheter **3107.** The catheter **3107** terminates on the outer side of needle **3109.** As shown in Fig. 32, the needle **3109** may be designed to be introduced on the promontory bone or in the semicircular canal of the inner ear after partial thinning of the bone. The needle **3109** may include a barbed outer surface and an anchoring device **3201** for providing bone anchoring. The needle **3109** may also include a conical stopper **3113** located at a short distance from the tip of the needle.

Fig. 33 is a graphical illustration of an implantable access port which may be used with the embodiments of Figs. 31 and 32. The access port includes an input septum **3301** which may be made of compressed silicone, a micro-reservoir **3303** and a port needle **3307.** The port needle **3307** may be anchored to the access port with metallic rings **3305** embedded in the silicone. The port needle **3307** may be partially covered with silicone and may have an outlet in its tip or in a side surface. The port needle **3307** may be introduced in the fluid of the inner ear after partial removal of the bony cover with a drill. In accordance with related embodiments, the port needle **3107** may be partially inserted in the posterior tympanotomy with the input septum **3301** and micro-reservoir **3303** in the mastoidectomy.

Fig. 34 is a graphical illustration showing that the implantable access port may be connected to the apparatus described with respect to Fig. 31 and/or the needle described and shown in Fig. 32.

As noted above, the invention and its embodiments described herein are not limited to application to the inner ear. Other applications, such as anywhere in the body where it is desirable to have a pump and a delivery catheter with or without electrical stimulation, are also possible with the use of this connecting system. For instance, it may be that such a connection is made on or in the skull at a preferred location for fluid delivery to some location in the brain.

While the invention has been described in connection with specific embodiments thereof, it will be understood that it is capable of further modification. This application is intended to cover any variation, uses, or adaptations of the invention and including such departures from the present disclosure as come within known or customary practice in the art to which invention pertains.

What is claimed is:

1. A fluid delivery system comprising:

an implantable fluid source;

a first catheter in fluid communication with the implantable fluid source; and

an implantable micro-valve in fluid communication with the first catheter.

2. A fluid delivery system according to claim 1, wherein the implantable fluid source includes a reservoir.

3. A fluid delivery system according to claim 2, wherein the reservoir is refillable.

4. A fluid delivery system according to claim 1, wherein the implantable fluid source includes a pump.

5. A fluid delivery system according to claim 4, wherein the pump is an osmotic pump.

6. A fluid delivery system according to claim 1, further comprising a second catheter in fluid communication with the implantable micro-valve.

7. A fluid delivery system according to claim 1, where in the implantable micro-valve includes a magnet.

8. A fluid delivery system according to claim 1, wherein the implantable micro-valve is self-closing.

9. A fluid delivery system according to claim 1, further comprising a switch for stopping fluid flow through the system.

10. A fluid delivery system according to claim 1, further comprising an electrode in communication with the fluid source.

11. A fluid delivery system according to claim 1, further comprising an electrode in communication with the first catheter.

12. A fluid delivery system according to claim 1, further comprising a cochlear implant in communication with the fluid source.

13. A fluid delivery system according to claim 1, further comprising a cochlear implant in communication with the first catheter.

14. A fluid delivery system comprising:

an implantable fluid source; and

an implantable micro-valve in fluid communication with the fluid source.

15. A fluid delivery system according to claim 14, wherein the fluid source is a canister which may be removed from the system.

16. An electrode for an implantable prosthesis, the electrode comprising:

a flexible front end including one or more metal contacts; and

a back end including one or more metal contacts

wherein the flexible front end is substantially thinner than the back end such that forces required to introduce the flexible front end to soft tissue are minimal.

17. An electrode according to claim 16, wherein the flexible front end and the back end are comprised of a polymer matrix.

18. An electrode according to claim 17, wherein each of the metal contacts is connected to a wire that runs through the polymer matrix.

19. An electrode according to claim 16, wherein the flexible front end comprises about one half the mass of the back end.

20. An electrode according to claim 16, further comprising one or more fluid outlets.

21. An electrode according to claim 20, wherein each of the one or more fluid outlets is in communication with at least two fluid channels.

22. An electrode according to claim 16, wherein the back end includes at least two segments, the two segments being fully connected to one another prior to implantation and at least partially disconnected from one another following implantation.

23. An electrode according to claim 16, further comprising a stopper disposed upon an outer wall of the electrode for limiting the extent of implantation.

24. An electrode according to claim 16, further comprising a connector disposed between the flexible front end and the back end such that the flexible front end may be separated from the back end.

25. A cochlear implant comprising:

an implantable housing, the implantable housing including an current source;

an electric lead in communication with the current source, the electric lead including a fluid delivery channel; and

an electrode array, the electrode array including one or more fluid outlets is in communication with the fluid delivery channel.

26. An implantable catheter for fluid delivery comprising:

a flexible polymer based housing having an internal channel in fluid communication with an implantable fluid source; and

one or more outlets disposed on the housing, each of the outlets including at least two outlet channels.

27. An implantable catheter according to claim 26, further comprising an adjustable blocker for closing an incision through which the catheter is inserted.

28. An implantable catheter according to claim 26, further comprising a reinforcing filament for increasing ease of implantation.

29. An implantable catheter according to claim 28, wherein the reinforcing filament includes a wire.

30. An implantable catheter according to claim 28, wherein the reinforcing filament includes a hardened polymer.

31. A micro-septum connector comprising:

an implantable port connector having a septum; and

an implantable spear connector having a needle for insertion into the septum.

32. A micro-septum connector according to claim 31, wherein the implantable port connector comprises:

a fluid source in fluid communication with the needle;

a compression ring for compressing the septum; and

a mechanism for guiding the needle as it is inserted into the septum.

33. A micro-septum connector according to claim 31, further comprising:

a stopping device for preventing direct contact between the implantable port connector and the implantable spear connector; and

a locking device for preventing disengagement of the needle from the septum.

34. A micro-septum connector according to claim 31, further comprising:

a port catheter in fluid communication with the implantable port connector.

35. A micro-septum connector according to claim 34, further comprising:

a bacterial filter disposed between the fluid source and port catheter.

36. A micro-septum connector according to claim 34, further comprising:

a bacterial filter disposed between the implantable port connector and the port catheter.

37. A micro-septum connector according to claim 31, further comprising:

a spear catheter in fluid communication with the needle.

38. An apparatus for delivering fluid to the body of a subject comprising:

an implantable fluid source;

a first catheter in fluid communication with the fluid source; and

a micro-septum connector, the micro-septum connector comprising:

an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle; and

an implantable port connector having a septum into which the needle is

inserted.

39. An apparatus according to claim 38, further comprising:

a second catheter in fluid communication with the implantable port connector.

40. An apparatus according to claim 38, wherein the fluid source is a fluid pump.

41. An apparatus according to claim 38, wherein the fluid source is a reservoir.

42. An apparatus for delivering fluid to the body of a subject comprising:

a first catheter in fluid communication with a fluid source;

a micro-septum connector, the micro-septum connector including an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle, and an implantable port connector having a septum into which the needle is inserted;

a second catheter in fluid communication with the implantable port connector; and

an implantable electronic prosthesis having one or more fluid channels is in fluid communication with the second catheter.

43. An apparatus for delivering fluid to the inner ear of a subject comprising:

a first catheter in fluid communication with a fluid source;

a micro-septum connector, the micro-septum connector including an implantable spear connector in communication with the first catheter, the implantable spear connector including a needle, and an implantable port connector having a septum into which the needle is inserted; and

a fixation device for affixing the implantable port connector to the inner ear of a subject.

44. An apparatus according to claim 43, further comprising:

a second catheter in fluid communication with the implantable port connector.

45. An apparatus according to claim 44, further comprising:

an electrode having one or more fluid channels in fluid communication with the second catheter.

46. An apparatus according to claim 43, wherein the fixation device is affixed to a promontory bone of the subject.

47. An apparatus for delivering fluid to the body of a subject comprising:

an implantable fluid reservoir, the implantable fluid reservoir including a first septum;

a catheter in fluid communication with the implantable fluid reservoir; and

a first needle in fluid communication with the catheter.

48. An apparatus according to claim 47, further comprising:

a bacterial filter disposed between the implantable fluid reservoir and the catheter.

49. An apparatus according to claim 47, further comprising:

a flow restrictor disposed between the implantable fluid reservoir and the catheter.

50. An apparatus according to claim 47, further comprising:

an anchor for affixing the first needle to the catheter.

51. An apparatus according to claim 48, wherein the anchor includes a silicone plug.

52. An apparatus according to claim 48, wherein the anchor includes one or more metal rings.

53. An apparatus according to claim 47, further comprising:

an access port in fluid communication with the first needle, the access port comprising:

a second septum, the second septum including a micro reservoir; and

a second needle in fluid communication with the micro reservoir.

54. An apparatus according to claim 53, further comprising:

an anchor for affixing the second needle to the second septum.

55. An apparatus according to claim 54, wherein the anchor includes one or more metal rings.

56. An apparatus according to claim 55, wherein the metal rings are embedded in silicone.

57. An implantable access port for delivering fluid to the body of a subject comprising:

an implantable septum, the implantable septum including a micro reservoir; and

a needle in fluid communication with the micro-reservoir.

58. An implantable access port according to claim 57, further comprising an anchor for affixing the needle to the implantable septum.

59. An implantable access port according to claim 58, wherein the anchor includes one or more metal rings.

60. An implantable access port according to claim 59, wherein the metal rings are embedded in silicone.

61. An implantable fluid source for delivery of fluid to the body of a subject comprising:

an implantable fluid reservoir, the implantable fluid reservoir having at least one fluid channel; and

a septum in fluid communication with the at least one fluid channel.

62. An implantable fluid source according to claim 61, further comprising:
a bacterial filter in fluid communication with the at least one fluid channel.

63. An implantable fluid source according to claim 61, further comprising:
a flow constrictor in fluid communication with the at least one fluid channel.

5

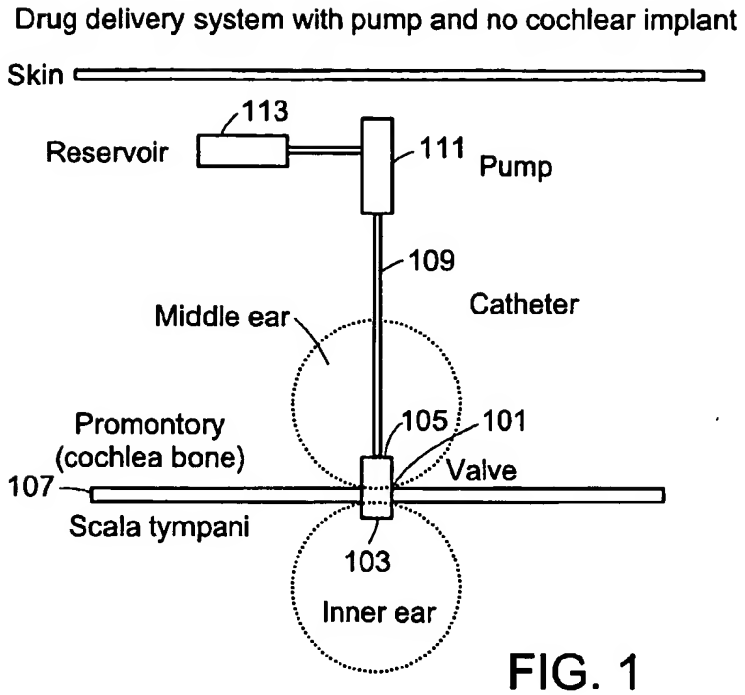
Drug delivery system with pump and no cochlear implant
Skin
113
Reservoir
111
Pump
109
Catheter
Middle ear
Promontory
(cochlea bone)
105
101
Valve
107
Scala tympani
103
Inner ear

FIG. 1

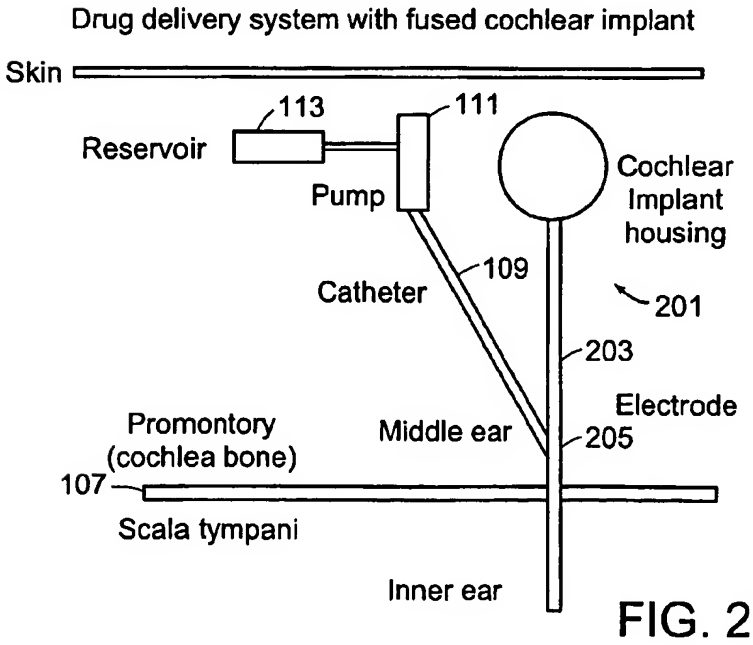
Drug delivery system with fused cochlear implant
Skin
113
111
Reservoir
Pump
Cochlear
Implant
housing
109
Catheter
201
203
Electrode
Promontory
(cochlea bone)
Middle ear
205
107
Scala tympani
Inner ear

FIG. 2

Drug delivery system in parralel with a cochlear implant

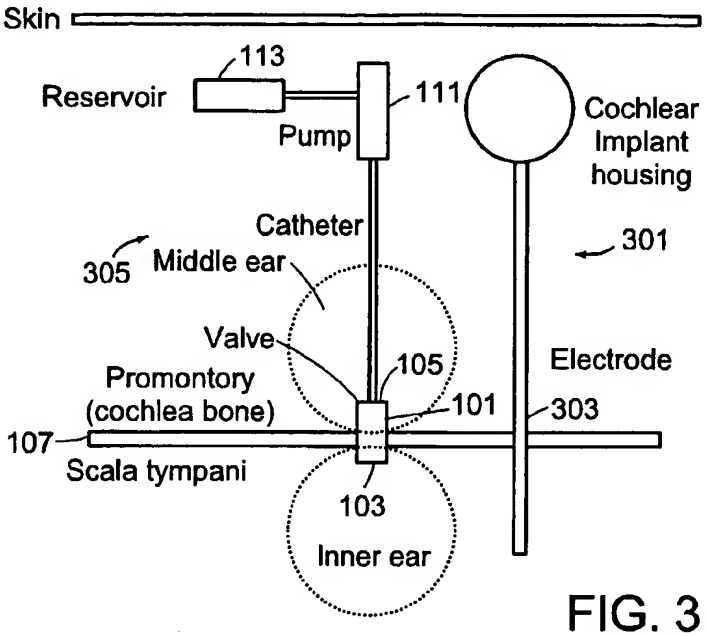

FIG. 3

Drug delivery system with active reservoir only

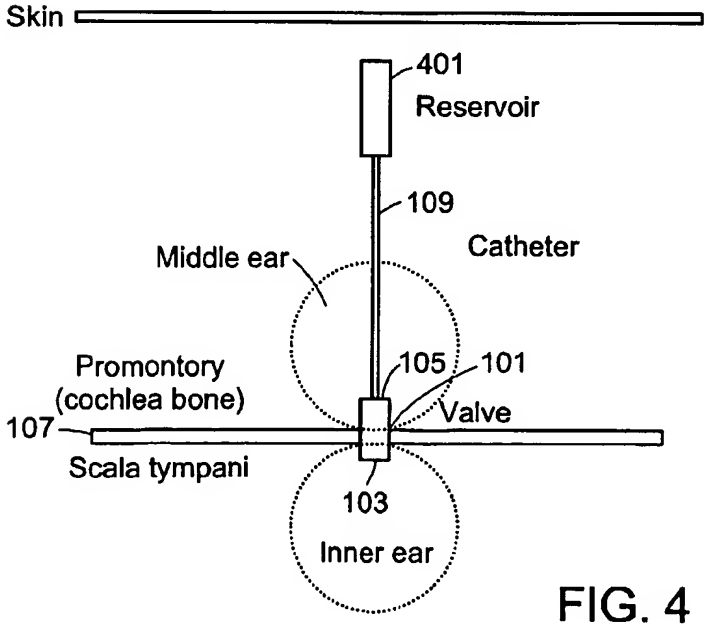

FIG. 4

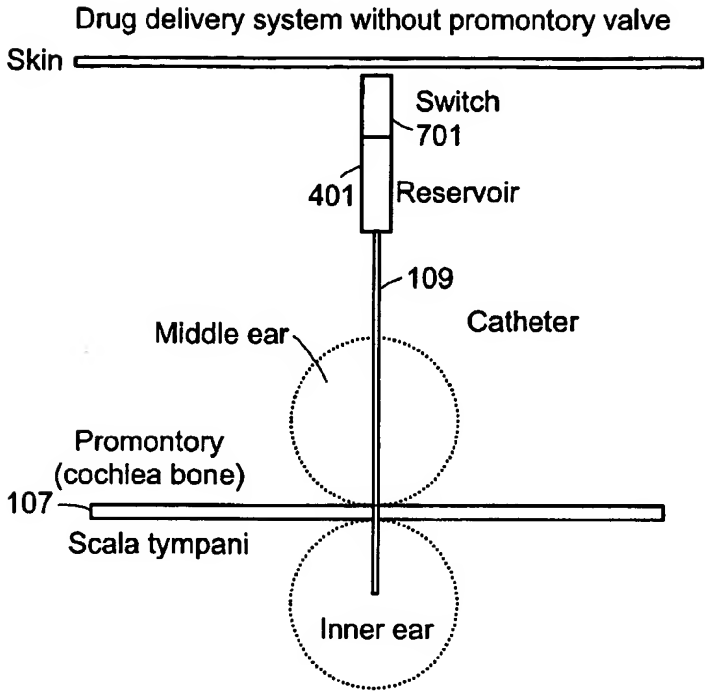
Drug delivery system without promontory valve
Skin
Switch
701
401
Reservoir
109
Catheter
Middle ear
Promontory
(cochlea bone)
107
Scala tympani
Inner ear

FIG. 5

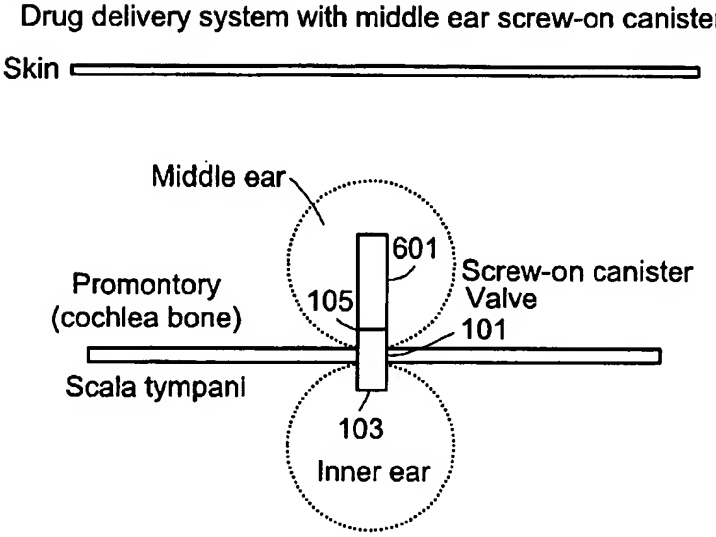
Drug delivery system with middle ear screw-on canister
Skin
Middle ear
601
Screw-on canister
Valve
Promontory
(cochlea bone)
105
101
Scala tympani
103
Inner ear

FIG. 6

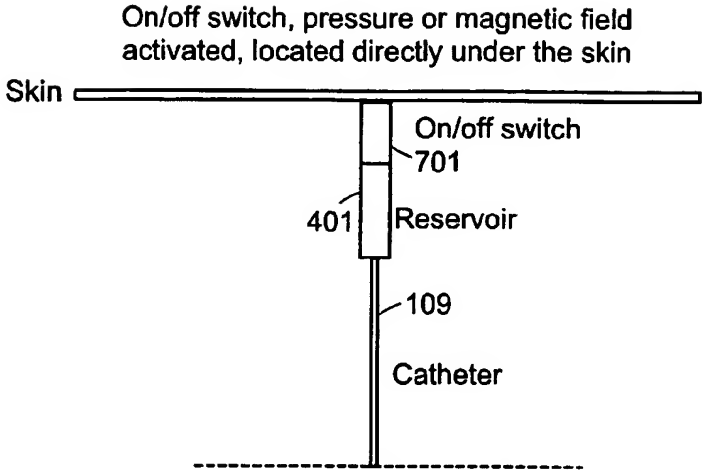
On/off switch, pressure or magnetic field activated, located directly under the skin
Skin
On/off switch
701
401
Reservoir
109
Catheter

FIG. 7

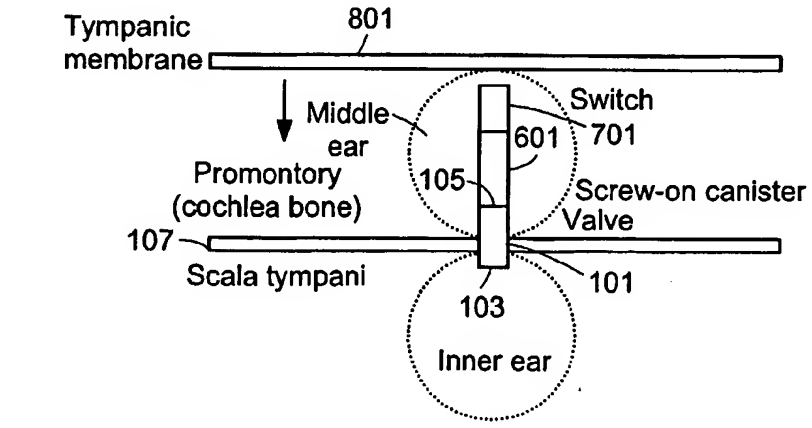
On/off switch, pressure or magnetic field activated, located in the middle ear
Tympanic membrane
801
Middle ear
Switch
701
601
Promontory (cochlea bone)
105
Screw-on canister
Valve
107
Scala tympani
101
103
Inner ear

FIG. 8

Example of a refillable reservoir

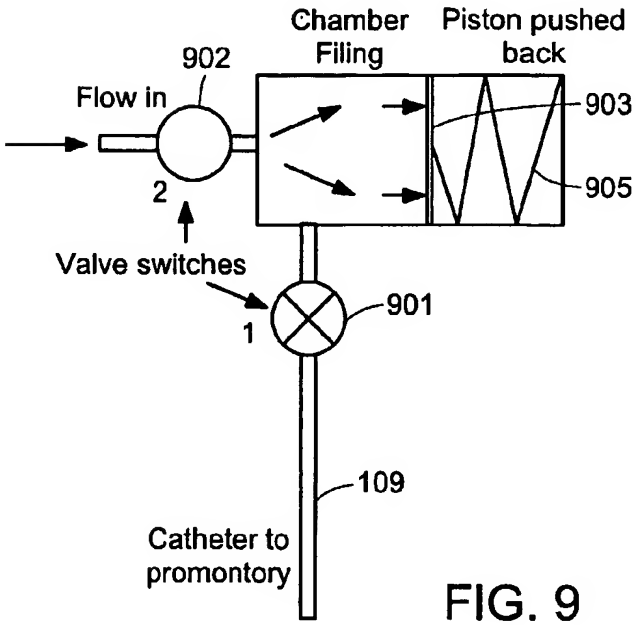

FIG. 9

Example of a self closing promontory valve

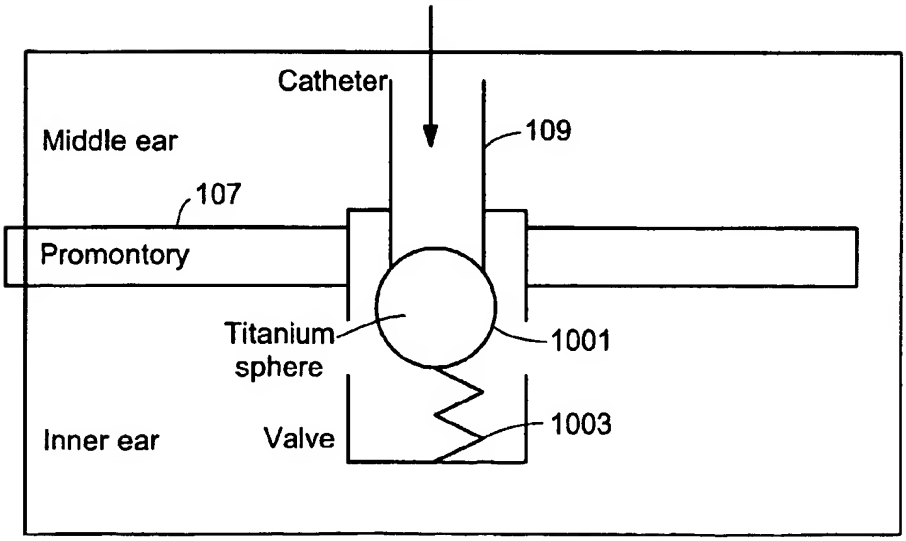

FIG. 10

Drug delivery system through the tympanic membrane

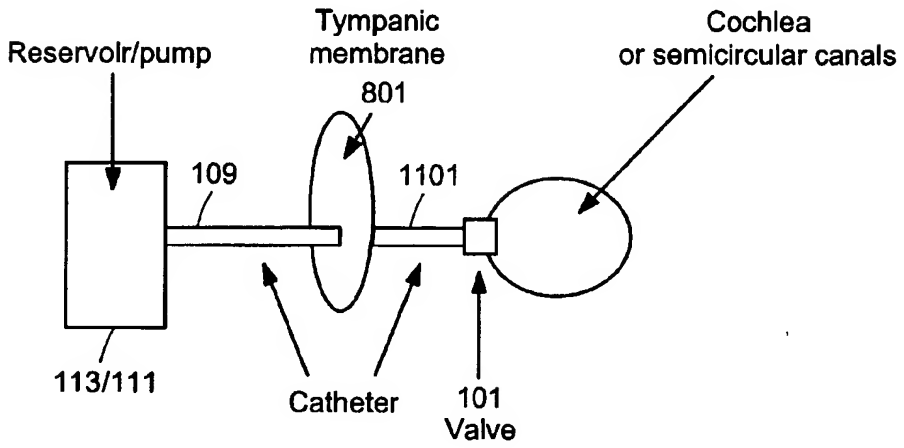

FIG. 11

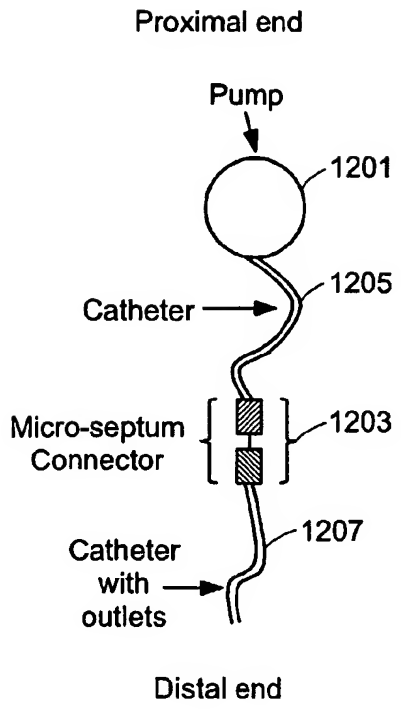

FIG. 12

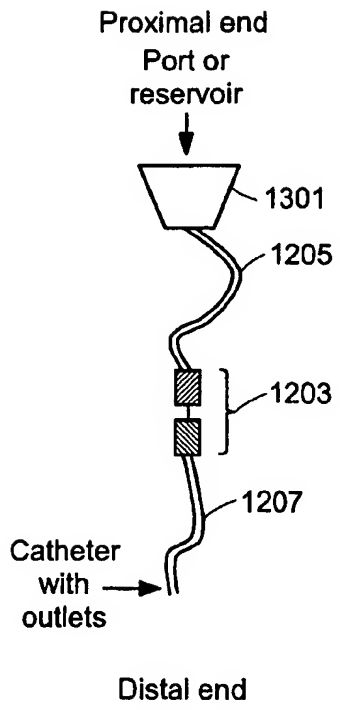

FIG. 13

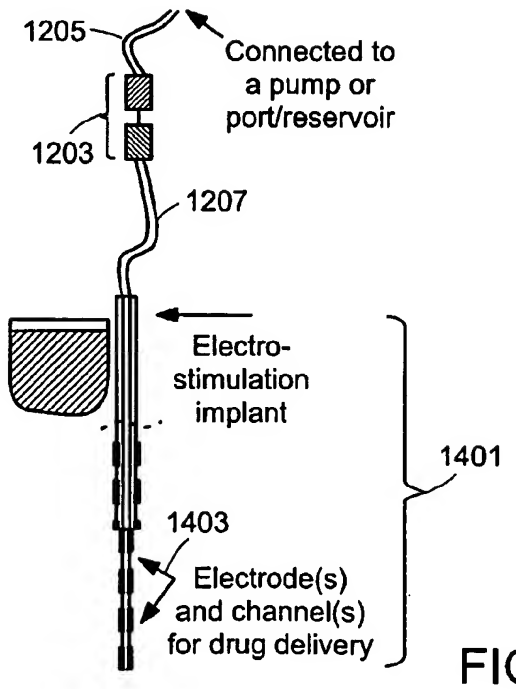

FIG. 14

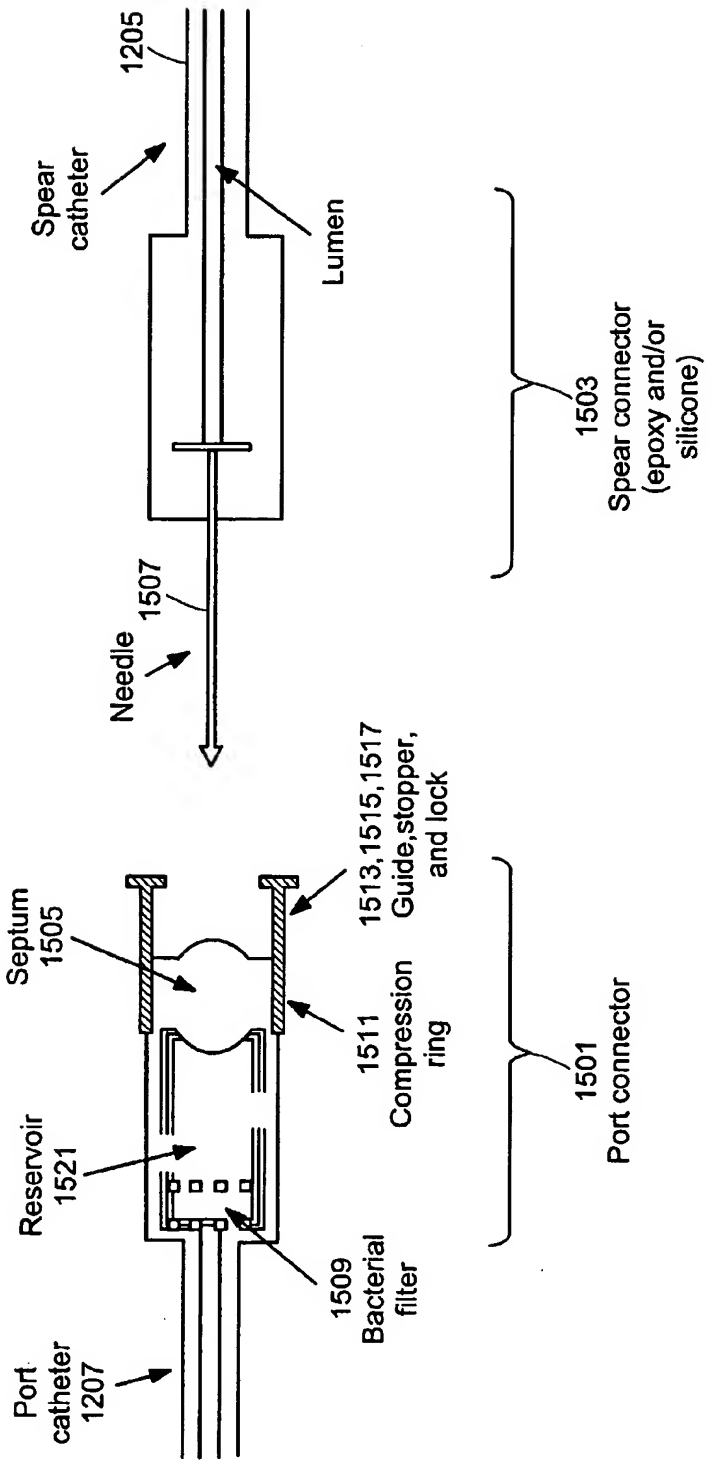
1205
Spear catheter
Lumen
1503
Spear connector (epoxy and/or silicone)
1507
Needle
1513,1515,1517
Guide,stopper, and lock
Septum 1505
1511
Compression ring
Reservoir 1521
1501
Port connector
1509
Bacterial filter
Port catheter 1207

FIG. 15

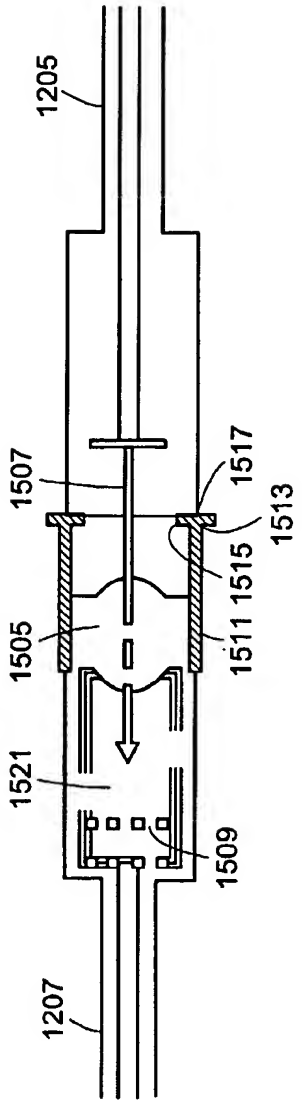

FIG. 16

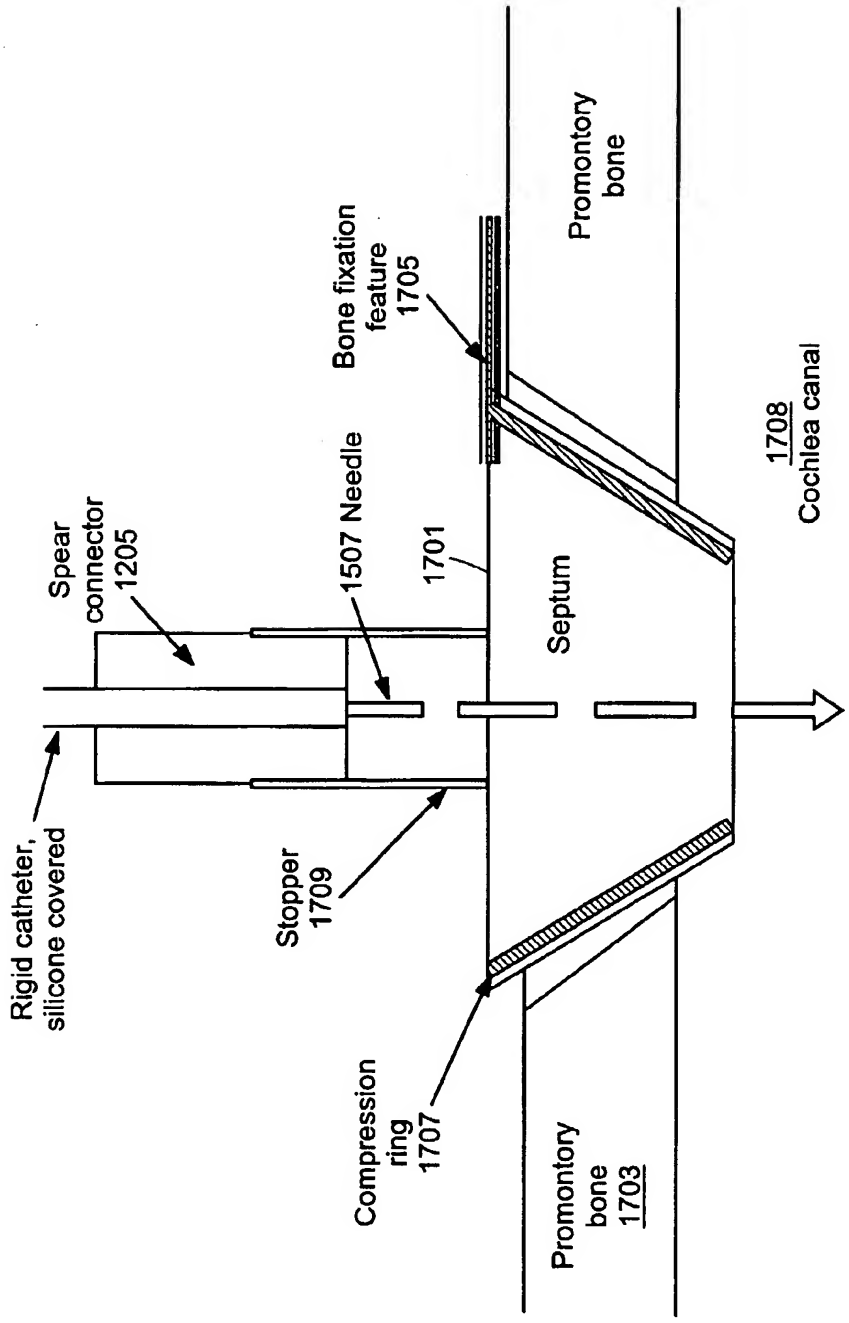
Promontory bone
Bone fixation feature 1705
1708 Cochlea canal
Spear connector 1205
1507 Needle
1701
Septum
Rigid catheter, silicone covered
Stopper 1709
Compression ring 1707
Promontory bone 1703

FIG. 17

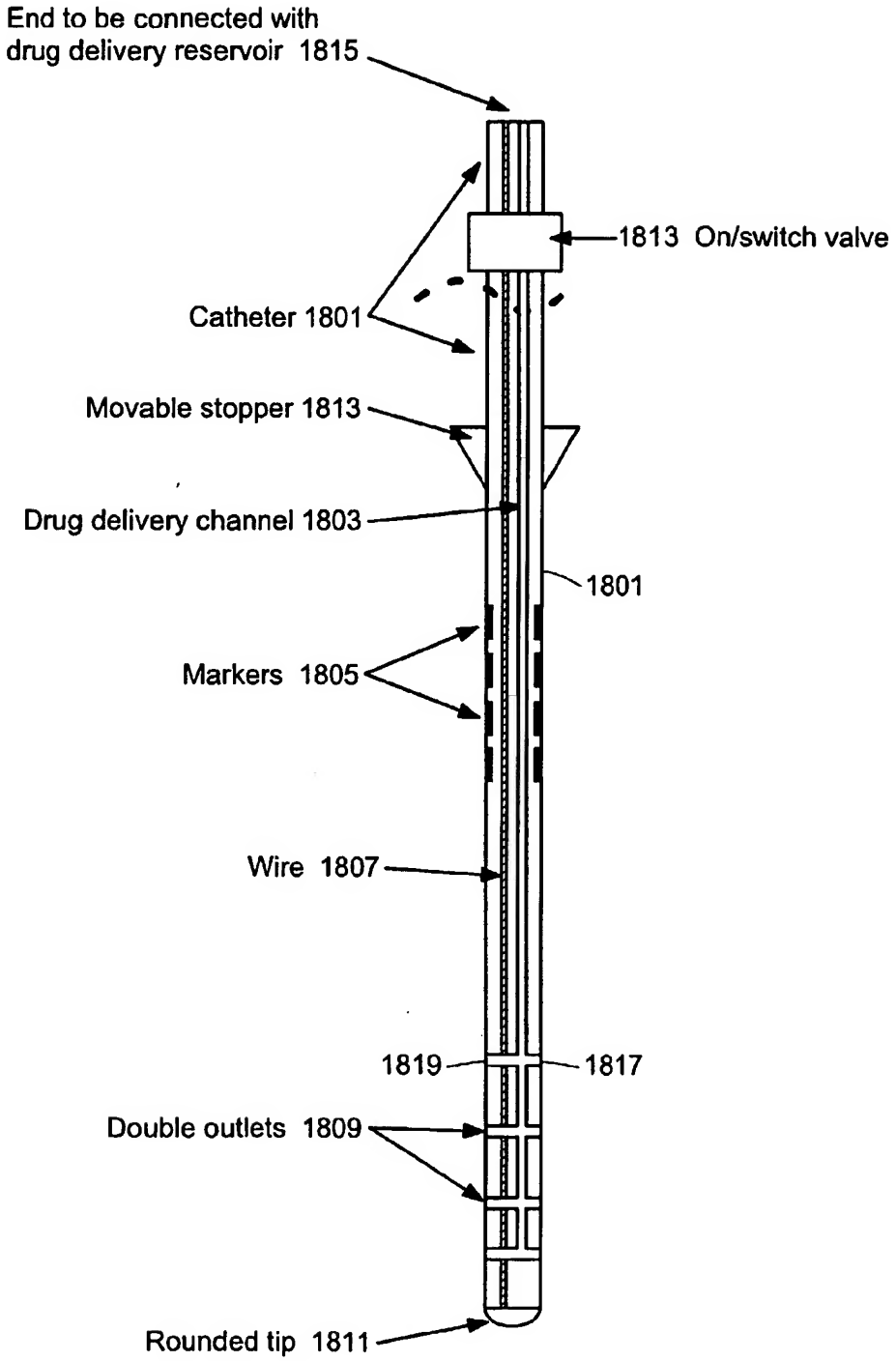
End to be connected with
drug delivery reservoir 1815
1813 On/switch valve
Catheter 1801
Movable stopper 1813
Drug delivery channel 1803
1801
Markers 1805
Wire 1807
1819
1817
Double outlets 1809
Rounded tip 1811

FIG. 18

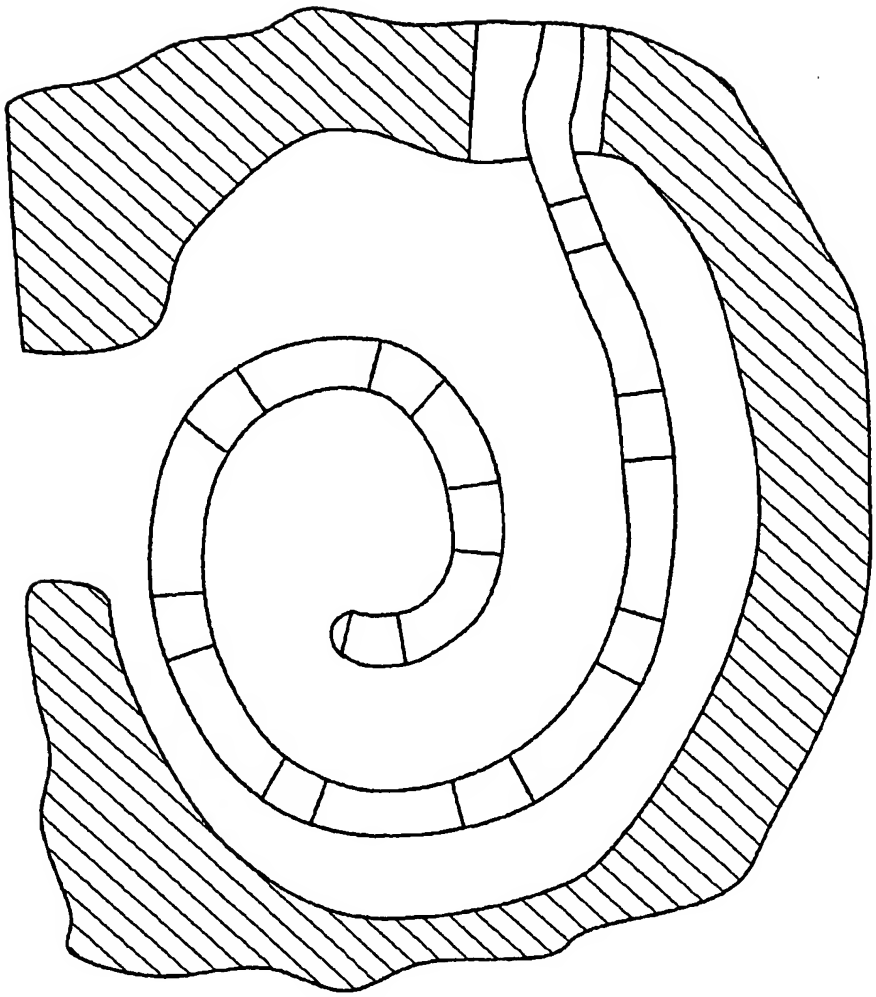

FIG. 19

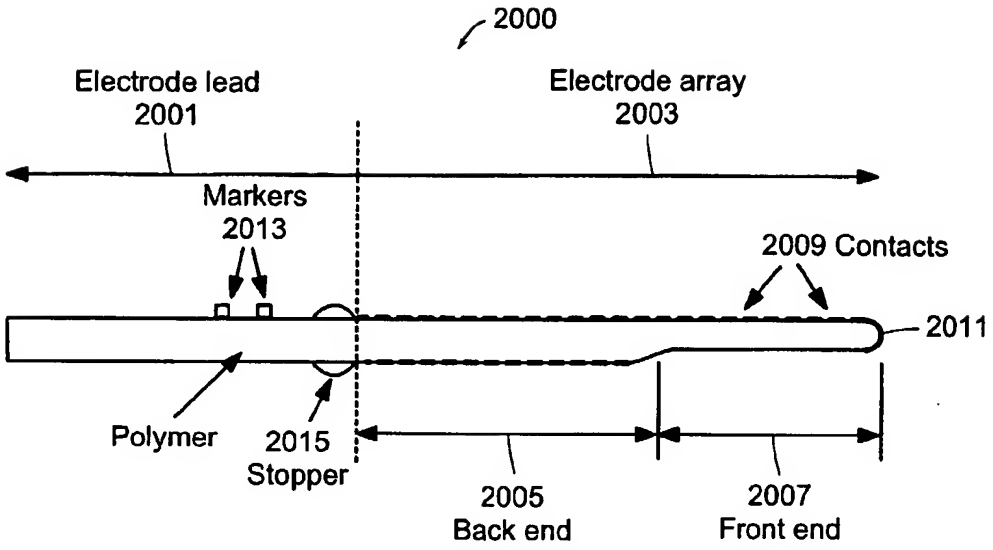
2000
Electrode lead
2001
Electrode array
2003
Markers
2013
2009 Contacts
2011
Polymer
2015
Stopper
2005
Back end
2007
Front end

FIG. 20

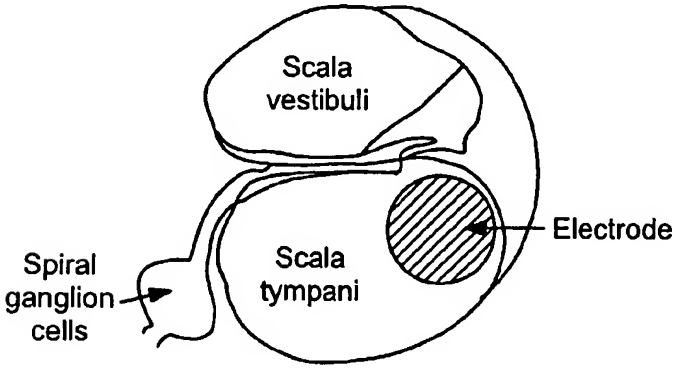
Scala
vestibuli
Electrode
Scala
tympani
Spiral
ganglion
cells

FIG. 21

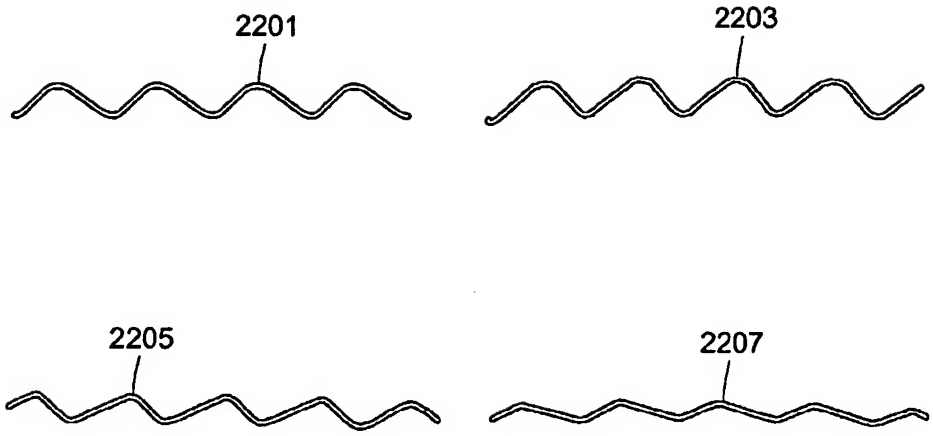
2201
2203
2205
2207

FIG. 22

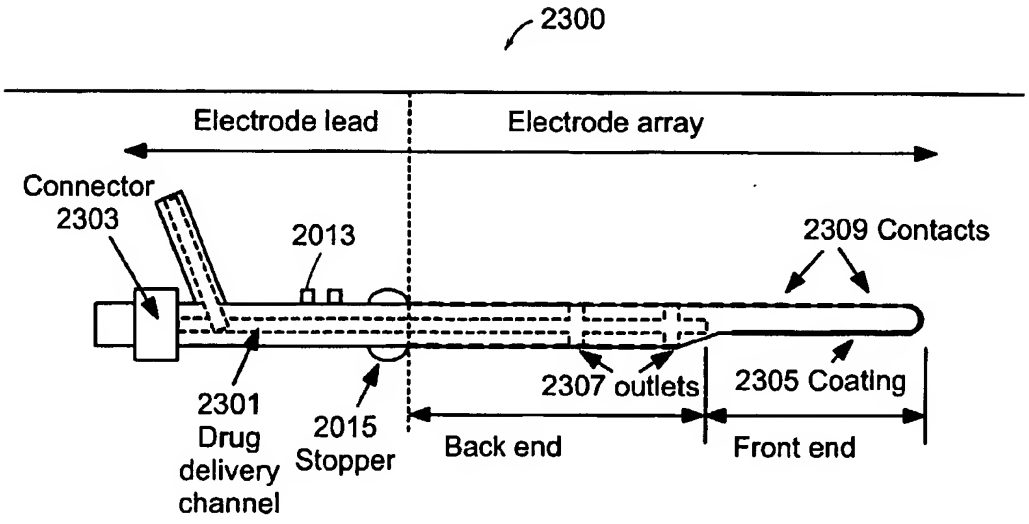
2300
Electrode lead
Electrode array
Connector
2303
2013
2309 Contacts
2307 outlets
2305 Coating
2301
Drug
delivery
channel
2015
Stopper
Back end
Front end

FIG. 23

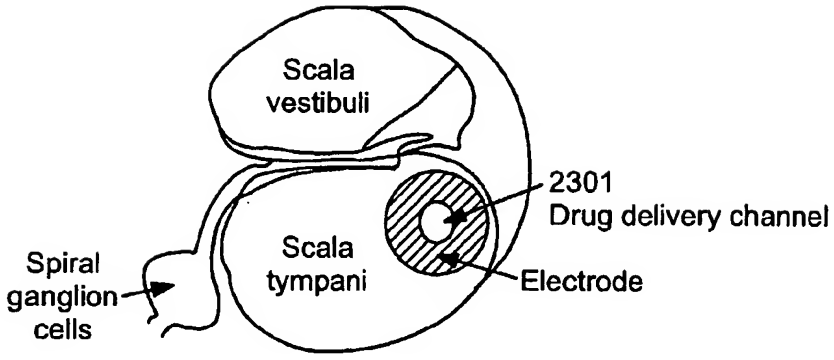
Scala
vestibuli
2301
Drug delivery channel
Scala
tympani
Electrode
Spiral
ganglion
cells

FIG. 24

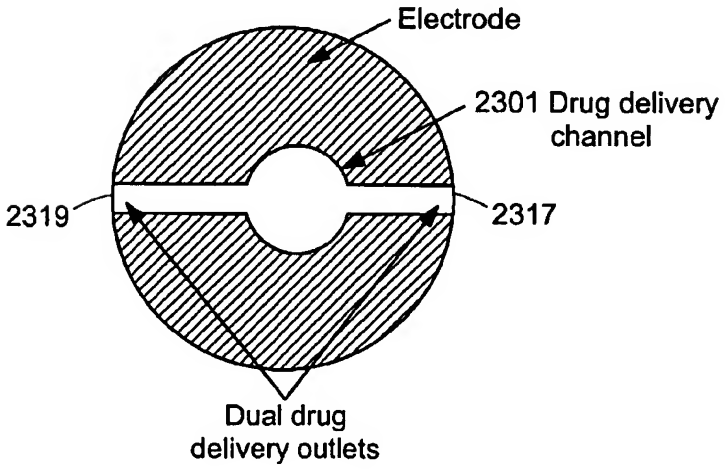
Electrode
2301 Drug delivery
channel
2319
2317
Dual drug
delivery outlets

FIG. 25

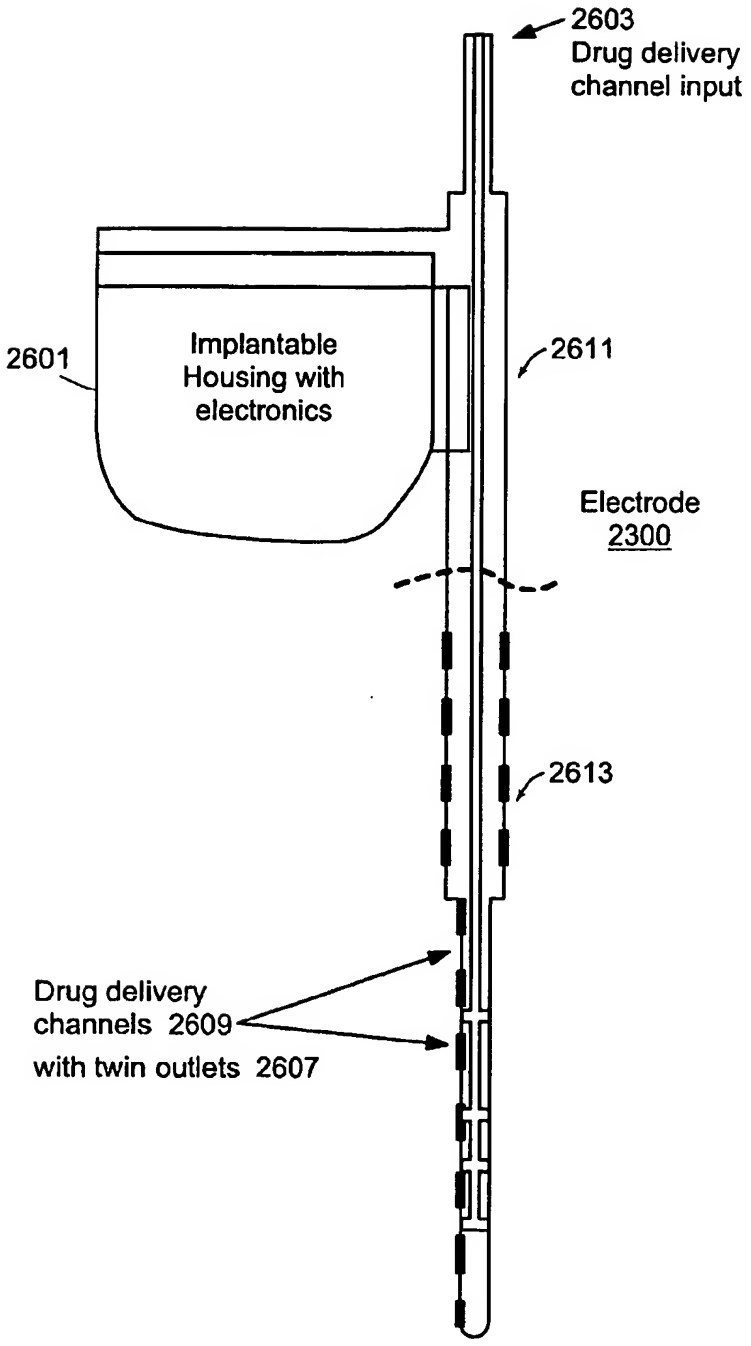
2603
Drug delivery
channel input
2601
Implantable
Housing with
electronics
2611
Electrode
2300
2613
Drug delivery
channels 2609
with twin outlets 2607

FIG. 26

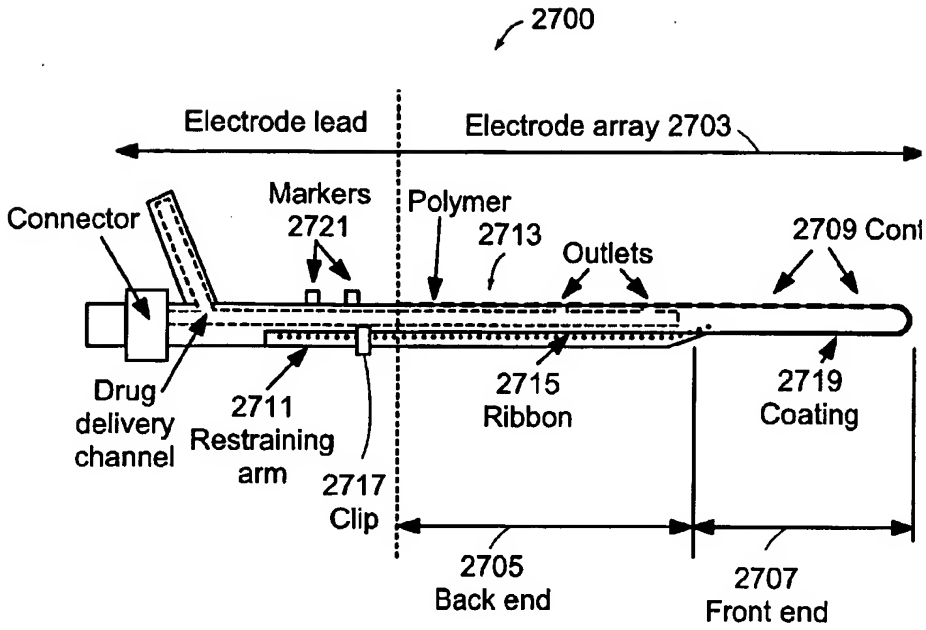

FIG. 27

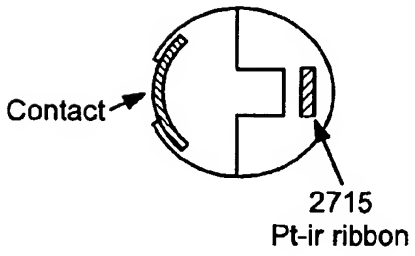

FIG. 28

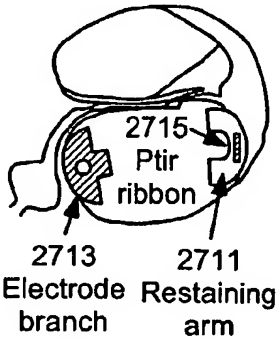

FIG. 29

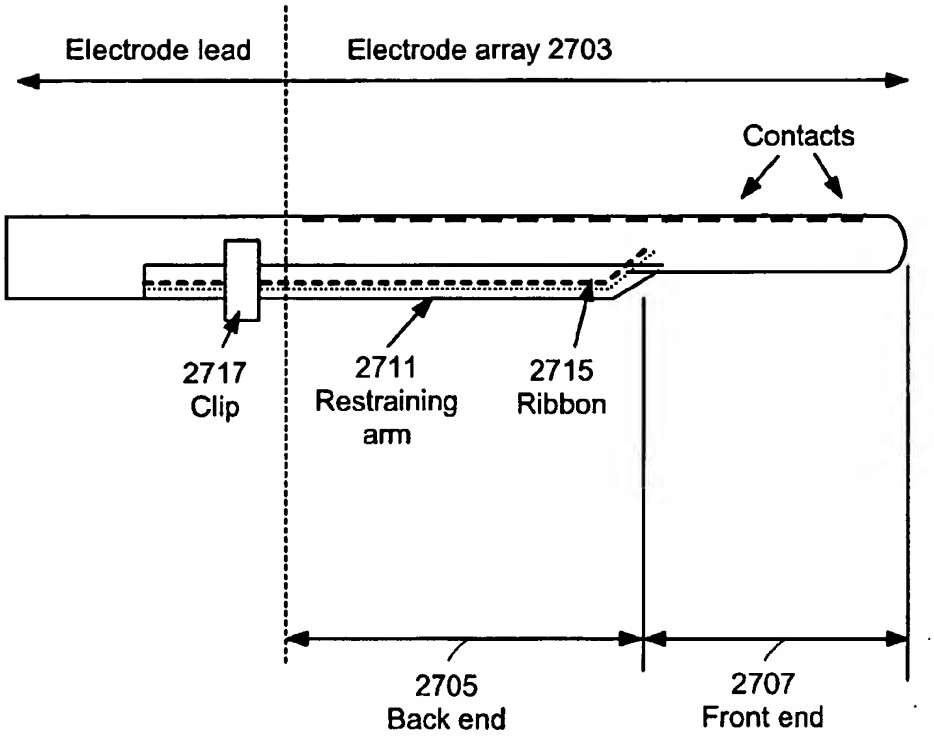
Electrode lead
Electrode array 2703
Contacts
2717
Clip
2711
Restraining
arm
2715
Ribbon
2705
Back end
2707
Front end

FIG. 30

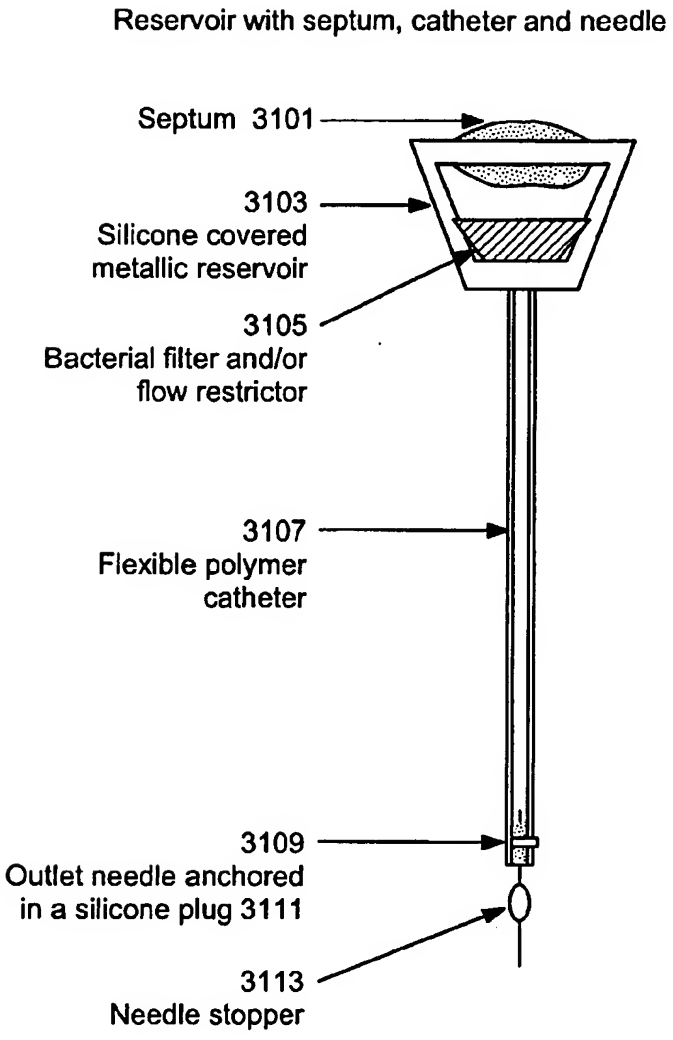
Reservoir with septum, catheter and needle
Septum 3101
3103
Silicone covered metallic reservoir
3105
Bacterial filter and/or flow restrictor
3107
Flexible polymer catheter
3109
Outlet needle anchored in a silicone plug 3111
3113
Needle stopper

FIG. 31

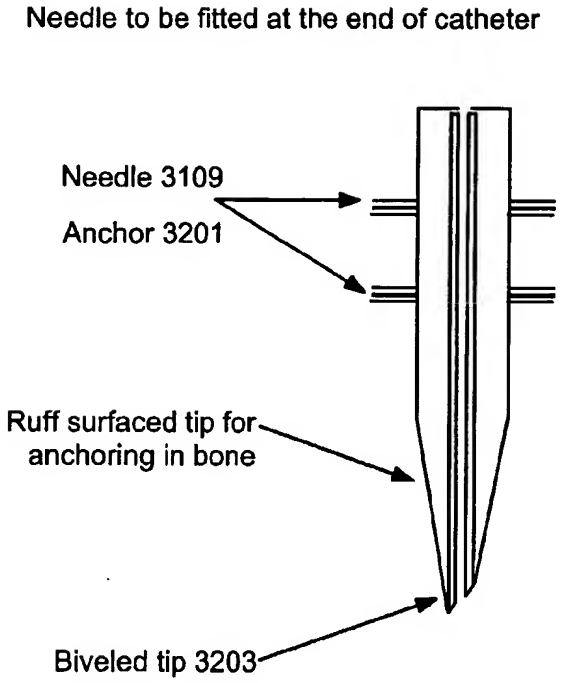
Needle to be fitted at the end of catheter
Needle 3109
Anchor 3201
Ruff surfaced tip for anchoring in bone
Biveled tip 3203

FIG. 32

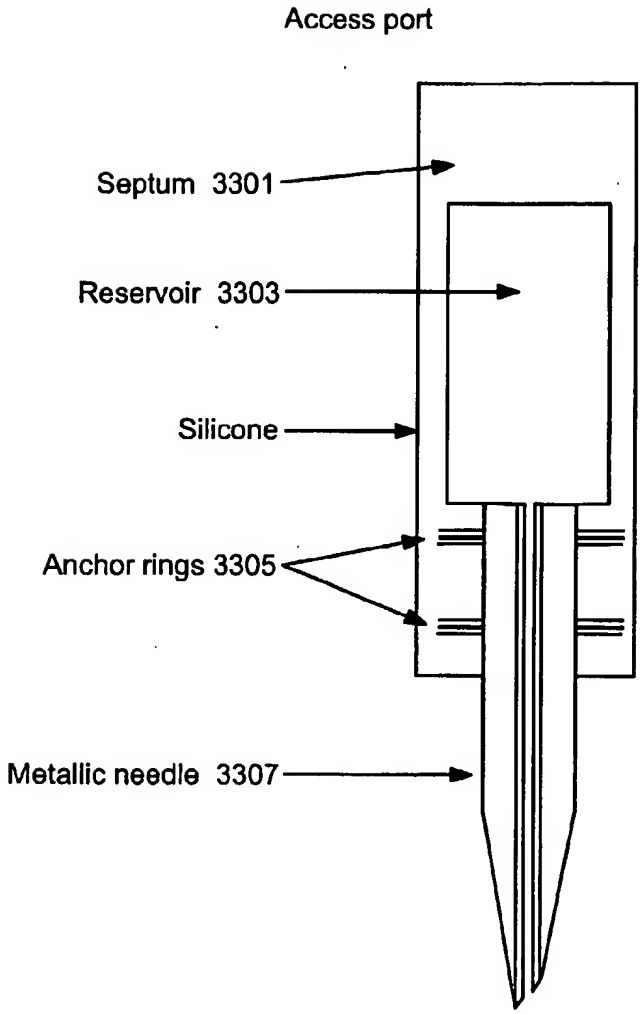
Access port
Septum 3301
Reservoir 3303
Silicone
Anchor rings 3305
Metallic needle 3307

FIG. 33

Connection between drug delivery device and access port

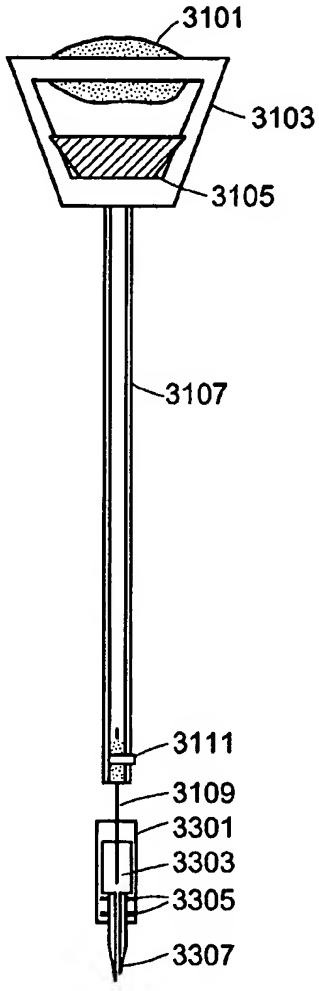

FIG. 34

INTERNATIONAL SEARCH REPORT

Int[illegible]nal Application No
PCT/IB 02/04731

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F11/04 A61N1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 99 00067 A (UNIV IOWA RES FOUND) 7 January 1999 (1999-01-07) page 84, line 20 -page 87, line 12; figures 23-26 ---	1-11, 16-25
Y	US 6 259 951 B1 (KUZMA JANUSZ A ET AL) 10 July 2001 (2001-07-10) column 11, line 5 - line 10; figure 2 ---	1-25
Y	US 4 053 952 A (GOLDSTEIN SETH R) 18 October 1977 (1977-10-18) abstract; figures 1,2 ---	1-25
X	US 5 458 631 A (XAVIER RAVI) 17 October 1995 (1995-10-17) column 7, line 45 -column 8, line 20; figure 5 --- -/--	26

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 February 2003	06/03/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Ehrsam, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Int ›nal Application No
PCT/IB 02/04731

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the rolevant passages	Relevant to claim No.
P,X	US 6 309 410 B1 (BATTMER ROLF-DIETER ET AL) 30 October 2001 (2001-10-30) the whole document	1-25

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 26-63

In view of the large number and also the wording of the claims presently on file, which render it difficult, if not impossible, to determine the matter for which protection is sought, the present application fails to comply with the clarity and conciseness requirements of Article 6 PCT (see also Rule 6.1(a) PCT) to such an extent that a meaningful search is impossible. Consequently, the search has been carried out for those parts of the application which do appear to be clear and concise.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 02/04731

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 26-63
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter...nal Application No
PCT/IB 02/04731

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
WO 9900067	A	07-01-1999	US	6129685 A	10-10-2000
			AU	8154698 A	19-01-1999
			EP	0991366 A1	12-04-2000
			JP	2002508690 T	19-03-2002
			WO	9900067 A1	07-01-1999
US 6259951	B1	10-07-2001	AU	4712900 A	05-12-2000
			EP	1185331 A1	13-03-2002
			WO	0069512 A1	23-11-2000
			AU	4846000 A	05-12-2000
			EP	1185332 A1	13-03-2002
			WO	0069513 A1	23-11-2000
			US	6309410 B1	30-10-2001
US 4053952	A	18-10-1977	NONE		
US 5458631	A	17-10-1995	US	5119832 A	09-06-1992
US 6309410	B1	30-10-2001	US	6038484 A	14-03-2000
			US	6078841 A	20-06-2000
			US	6129753 A	10-10-2000
			US	6119044 A	12-09-2000
			US	6195586 B1	27-02-2001
			US	6149657 A	21-11-2000
			US	6144883 A	07-11-2000
			US	6304787 B1	16-10-2001
			US	6163729 A	19-12-2000
			US	6397110 B1	28-05-2002
			US	6321125 B1	20-11-2001
			AU	4846000 A	05-12-2000
			EP	1185332 A1	13-03-2002
			WO	0069513 A1	23-11-2000
			US	6259951 B1	10-07-2001